

Frequency® 38

(polymacon)

Soft (Hydrophilic) Contact Lenses for Daily Wear

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 (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

CooperVision, Inc., Scottsville, NY 14546

DESCRIPTION:

The *Frequency 38* (polymacon) Hydrophilic Contact Lens for Daily Wear (tinted) is available as a single vision lens. The lens material, polymacon is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) cross-linked with ethyleneglycol dimethacrylate (62%) and water (38%). *Frequency 38* (polymacon) Hydrophilic Contact Lenses for Daily Wear are tinted for visibility purposes from edge to edge using color additive Blue No. 4.

Frequency 38 is a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera with the following dimensions:

- Diameter: 14.0mm to 15.0mm
- Base Curve: 8.4mm to 9.0mm
- Center Thickness: 0.03mm to 0.40mm (varies with power)
- Powers: -20.00 to +20.00D

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

The physical properties of the lens are:

- Refractive Index: 1.43
- Light Transmittance: >97%
- Specific Gravity: 1.17
- Water Content: 38%
- Oxygen Permeability: 8.0×10^{-11} (cm²/sec) (ml O₂/ml x mmHg) at 35°C (Fatt method for determination of oxygen permeability)

ACTIONS:

When placed on the cornea in its hydrated state, the *Frequency 38* lens acts a refracting medium to focus light rays on the retina.

INDICATIONS (USES):

Frequency 38 (polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 diopters that does not interfere with visual acuity.

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

CONTRAINDICATIONS (REASONS NOT TO USE):

Do not use *Frequency 38* lenses 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.
- 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 *Ascend* 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**.
- 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.
- Studies have been shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If the patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care practitioner.

PRECAUTIONS:

Special Precautions for Eye Care Practitioners

- Due to the small numbers of patients enrolled in clinical 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.
 - Aphakic patients should not be fitted with *Frequency 38* contact lenses 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 the dye and become discolored. Whenever fluorescein is used in the 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.

Eye care practitioners should carefully instruct patient's 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 lenses only.
 - 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 the 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 non-movement 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, deodorant, 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 the contact lenses with the finger 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 38* 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 hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing the 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 your hand.
- Do not touch the lens with fingernails.
- 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.
- *Frequency 38* when prescribed in a Frequent Replacement Program are intended to be disposed of at the end of the prescribed period. Therefore, it is important to always have available a pair of replacement lenses.

ADVERSE EFFECTS:

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

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye 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 the problem stops, then look closely at the lens. If the lens is in some way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect both lenses; then 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 *Frequency 38* contact lenses. For a detailed description of the fitting techniques, refer to the *Frequency 38* Professional Fitting and Information Guide, copies of which are available from:



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

WEARING SCHEDULE:

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

CooperVision recommends that the *Frequency 38* lens 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.

Frequency 38 lenses are indicated for daily wear (less than 24 hours, while awake). The maximum suggested wearing time is:

| Day | Hours | Day | Hours |
|-----|-------|-----|------------------|
| 1 | 4 | 7 | 10 |
| 2 | 5 | 8 | 11 |
| 3 | 6 | 9 | 12 |
| 4 | 7 | 10 | All Waking Hours |
| 5 | 8 | | |
| 6 | 9 | | |

Studies have not been completed to show that **Frequency 38** is safe to wear during sleep.

LENS CARE DIRECTIONS:

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 First Clean and Rinse, the Disinfect Lenses)

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh, unexpired** lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care systems **unless indicated on solution labeling**.
- 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 the solution labeling.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of enzyme or any cleaning solution does not substitute for disinfection.
- The eye care practitioner should recommend a care system that is appropriate for **Frequency 38** contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

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 instructions.

THERMAL (HEAT) DISINFECTING METHOD:

- After cleaning and thoroughly rinsing the lenses with the recommended solutions, prepare the empty lens storage case. To keep the lenses wet during disinfecting, use the solution that is recommended by the lens manufacturer and/or the eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.

- Put the lens storage case into the disinfecting unit and follow the disinfecting unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Emergency (Alternate) Method for Thermal (Heat) Disinfecting:

- If a heat disinfecting unit is not available, place the tightly closed storage container which contains the lenses into a pan of already boiling water. Leave the closed lens case in the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes) Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfecting of the lens.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Before insertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide):

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning** and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution 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 lenses 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 air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eye care practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS:

If a **Frequency 38** 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, the lens **should not be used unless it has been examined by the eye care practitioner.**

CARE FOR A STICKING (NONMOVING) LENS:

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues 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.**

IN OFFICE CARE REGIMEN FOR TRIAL LENSES:

Eye care practitioners should educate contact lens technicians concerning proper care of trial lenses.

Each contact lens is shipped sterile in a blister pack with sterile saline solutions. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the blister pack should not be opened until immediately prior to use. Lenses should be surface cleaned and disinfected prior to reusing in a diagnostic procedure or before dispensing to a patient.

Follow the disinfection procedures described above for proper disinfection of trial lenses.

FREQUENT REPLACEMENT PROGRAM:

For complete information concerning the Frequent Replacement Program, please refer to the Professional Fitting and Information Guide for **Frequency 38** contact lenses.

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, diopter power, manufacturing lot number, and expiration date of the lens.

DO NOT USE IF THE BLISTER IS DAMAGED OR SEAL IS BROKEN

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **Frequency 38** contact lens or experienced with the lenses should be reported to:



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

www.coopervision.com

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