

Aquamax Monthly disposable soft contact lens

CAUTION:

Federal (U.S.A) law restricts this device to sale or on the order of a licensed practitioner.

IMPORTANT:

This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses and recommended wearing schedule.

Long term exposure to UV radiation is a part of the risk factors associated with cataracts. Exposure is according to a number of factors for instance environmental conditions (geography, altitude) and personal factors (nature of outdoor activities). UV blocking contact lenses help to resist harmful UV radiation. In any case, clinical studies have not proved that wearing UV blocking contact lens decrease the risk factor associated with cataracts.

DESCRIPTION

The ionic lens material, Etafilcon A is a co-polymer of 2-Hydroxyethylmethacrylate (2-HEMA) and Methacrylic Acid (MAA). The copolymer consists of 42% Etafilcon A and 58% water by weight when immersed in buffered saline solution. The lens polymer contains a UV absorbing compound and is available clear or with a blue visibility-handling tint, color additive "reactive Blue19", 21 CFR part 73.3121. The Etafilcon A name has been adopted by the United States Adopted Names Council (USAN). A benzotriazole UV absorbing monomer is used to block UV radiation.

The handling tint is reactive blue 19, making the lens more visible when handling. The PEGAVISION contact lens tint may reduce slightly after repeated disinfection. Slight reduction in tint will not affect the safety or performance of the lens.

The physical/optical properties of the lens are:

Refractive index: 1.402

Light Transmittance: 95 % minimum.

Water Content: 58%

Oxygen Permeability (Dk):

19.73×10^{-11} (cm²/s){mLO₂ml/ (ml x mmHg)}

(NOTE SAME MATERIAL AS Daily)

The Aquamax Monthly Disposable Soft Contact Lens is a hemispherical shell of the following dimensions:

Type_1 Sphere & Aspheric

* Diameter: 13.8~14.5 ± 0.20mm

* Center Thickness:
0.08mm ~ 0.29mm
varies with power

* Base Curve: 8.1~9.0 ± 0.2mm

* Power :
+0.25 ~ +6.00 D Diopter (in 0.25D increment)
-0.25 ~ -6.00 D Diopter (in 0.25D increment)
-6.00 ~ -12.00D Diopter (in 0.50D increment)

Type_2 Toric

* Diameter: 13.8~14.5 ± 0.20mm

* Center Thickness:
0.08mm ~ 0.29mm
varies with power

* Base Curve: 8.1~9.0 ± 0.2mm

* Power :
+0.25 ~ +6.00 D Diopter (in 0.25D increment)
-0.25 ~ -6.00 D Diopter (in 0.25D increment)
-6.00 ~ -12.00D Diopter (in 0.50D increment)

*Cylinder Power :
-0.25 ~ -3.50D Diopter (in 0.25D increment)
*Axis: 0°~180° (90°、180°)

Type_3 Multifocal

Diameter: 13.8~14.5 ± 0.20mm

* Center Thickness:
0.08mm ~ 0.29mm
varies with power

* Base Curve: 8.1~9.0 ± 0.2mm

* Power :
+0.25 ~ +6.50 D Diopter (in 0.25D increment)
-0.25 ~ -6.00 D Diopter (in 0.25D increment)
-6.00 ~ -12.25D Diopter (in 0.50D increment)

*Add Power : +0.25D ~ +3.00D

INDICATION

Type_1 Sphere & Aspheric:

Aquamax Monthly Disposable Soft Contact Lens is indicated for daily wear for vision correction of refractive ametropia in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters (D) or less where the astigmatism does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +6.00D to -12.00D.

Type_2 Toric:

Aquamax Monthly Disposable Soft Contact Lens Toric Soft Contact Lenses are indicated for daily disposable wear for the correction of vision in people with non-diseased eyes who are nearsighted (myopic) or farsighted (hyperopic) and may have -0.25D ~ -3.50D of astigmatism.

Type_3 Multifocal:

Aquamax Monthly Disposable Soft Contact Lens Multifocal Contact Lenses are indicated for daily disposable wear for the correction of distance and

near vision in people with non-diseased eyes who may have +0.25D ~ +3.00D of ADD power.

Eye Care Practitioners may prescribe the lens for either single-use daily disposable wear or frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement as prescribed by the eye care professional. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical (not heat) lens care system only.

WARNING:

UV absorbing contact lenses aren't substitutes for protective UV absorbing eyewear for example UV absorbing goggles or sunglasses because they don't completely cover the eye and surrounding area. You should continue to use UV absorbing eyewear as directed.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the PEGAVISION Contact 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.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.

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, such as scarring and ulceration of the cornea resulting in loss of vision. It is essential that patients strictly compliance with the eye care practitioner's direction and all labeling instructions for correct use of lenses and lens care products.
- Studies have shown that contact lens wearers who are smokers have a higher risk Lens reactions than nonsmokers, especially when lenses are worn overnight or while sleeping.
- If a patient experiences eye discomfort, such as foreign body sensation, excessive tearing, vision changes, or redness of the eye or other problems .The patient should immediately remove lenses and promptly contact his or her eye care practitioner.

- Monthly 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 are increased when lenses are worn overnight.
- Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection.
- The need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient.
- Contact Lenses is not for to be re-sterilized. Do not re-sterilized then use it, otherwise it may cause serious injury to the eyes.

HANDLING OF LENSES

Verify that the lens is right side out. The lens should assume a natural, curved, bowl-like shape. If the lens edges tend to point outward, the lens is inside out. Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward. If the lens is inside out, the edges will turn slightly outward.

- Lens Orientation Correct



- Lens Orientation Incorrect (Lens Inside Out)



INSTRUCTION FOR USER

How to insert the lenses:

Step 1: Thoroughly wash and dry your hands with soap and a clean towel.

Step 2: Put the lens into your palm, remove lenses from case and pour contact solution on the lens, VERY GENTLY rubbing with your finger to remove any trace of debris.

Step 3: Place the lens on the tip of your index finger. Be sure the lens is correctly oriented by checking the inside-out marker follow as below the edges should turn inward. If the lens is inside out, the edges will turn slightly outward.



- Check the lens has no deposits, scratches or cosmetic signs.
- Rinse the lens with contact lens care solution and put it on the top of your forefinger.
- Makes sure the lens is in correction position.

Step 4: Use your other hand to hold your upper eyelid so you won't blink. Pull down your lower eyelid with the other fingers of your applying hand.

- See in front of you and keep the eyelids opened.
- Place the lens onto the center of your eye paying attention that no air remains under the lens and release the lower lid margin.
- Slowly release the upper lid and close your eye.
- If the lens is wrongly worn it will not be comfortable.
- Keep it out of the eye and try to wear it again later after having turned it over and rinsed with contact lens care solution.

STEP 5: Look to the side and gently place the lens on your eye. Slowly release your eyelid and close your eye for a moment, then slowly release your eye and blink a few times to center the lens.

- If your vision is still blurred, the lens could be probably worn in the wrong position, or may be dirty or, in case of corrective lenses, could be inverted (left instead of right)

STEP 6: If your lens feels uncomfortable, remove it and inspect for damage or debris. If it's damaged, discard it. Otherwise, try rinsing with more solution and turning it inside out in case you inserted it the wrong way.

- If the problem still occurs please see your eye doctor

STEP 7: Repeat instructions for the second lens.

How to remove your lenses:

STEP 1: Thoroughly wash and dry your hands with soap and a clean towel.

STEP 2: With your head straight, look up. Pull down your lower eye lid. Bring your index finger close to your eye until you touch the lower edge of the lens, then slide the lens to the lower part of your eye.

STEP 3: Keep the eyelid opened and hold the lens under the index finger, move your thumb so you can compress the lens slightly between the thumb and the index finger

- If you have difficulty removing the lens, place a few comfort eyedrops in the eye, wait a few minutes and try again

STEP 4: Remove the other lens following the same procedure.

- Monthly contact lenses (light blue handling tint and color) have to be disinfected regularly (please refer to LENS CARE PRECAUTION), and thrown away at the end of monthly use.

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 eye should be carefully monitored by the prescribing eye care practitioner.

- Fluorescein, a yellow dye, should not be used while the patient is wearing the lenses, because the lenses will absorb this dye and become discolored. Whenever fluorescein is used in eye, flush the eyes with sterile saline solution. Wait at least 10 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait at least 1 hour before wearing the lenses. If inserted too soon, the lenses may absorb remaining fluorescein.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have somebody else available who can remove the lenses for him or her.
- Eye Care Professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eye care professional should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions can't 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.
 - Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
 - Always use fresh, sterile unexpired solutions.
 - Always follow directions in the package 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 immersing lenses.
 - Always keep the lenses completely immersed in the recommended storage solution for contact lens when the lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried Out Lens.
- If the lens sticks (stops moving) on the eye, follow the recommended directions in 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, immediately consult your eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps,

creams, deodorants, aerosol products or hair sprays in the eyes or on the lenses. It is best to put on lenses before putting on make-up. Water-base cosmetics are less likely to damage lenses than oil-base products.

- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in INSTRUCTION FOR USER.
- Exposure to water while wearing contact lenses in activities such as swimming, water skiing, and hot tubs may increase the risk of ocular infection, including but not limited to *acanthamoeba* keratitis. Ask your eye care professional about wearing contact lenses during sporting activities.
- 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 gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- 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 discard lenses after the recommended wearing schedule prescribed by the eye care practitioner.
- 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.
- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so increases the risk of adverse effects.
- Do not use lenses past the expiration date.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution, patients using such medications accordingly and prescribe proper remedial measures.
- Oral contraceptive users could develop visual

change or change in lens tolerance when using lenses.

- Do not use if the sterile blister package is opened or damaged.
- Never allow anyone to wear your lenses. They have been prescribed to fit your eyes and to correct your vision to the degree necessary. Sharing lenses greatly increase the chance of eye infections.

ADVERSE REACTIONS (Problem and What To Do)

The patient should be informed that the following problems may occur when wearing contact lenses:

- Your eye stinging, burning, itching (irritation), or other eye pain.
- Comfort is less compared to when lens was first placed on eye.
- There may be feeling of something in the eye (foreign body, 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).
- Feeling of dryness.
- Foreign body sensation.

If the patient notices any of the above, he or she should be instructed to:

- Immediately remove 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 the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult the eye care practitioner.
- If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should immediately remove the lens and contact his or her eye care practitioner or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious eye damage. Additionally, contact lens wear may be associated with ocular changes which require consideration of discontinuation or restriction of wear. These include

but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing. (NOTE NOT EXTENDED WEAR)

FITTING

- The lens must move adequately on the eye for a suitable fit if the fit is judged to be too tight, the patient must be refit into a lens which provides the criteria of a well-fitted lens.
- Fitting techniques for other contact lenses may not be applicable to the fitting of these lenses.

WEARING SCHEDULE

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

Daily Wear:

There may be a tendency for the **NEW** daily wear patient to over-wear the lenses initially. Initial daily wearing schedule should be stressed to these patients.

The wearing schedule should be determined by the eye care practitioner. The maximum suggested wearing time for the PEGAVISION contact lens is:

DAY	1	2	3	4	5	6
HOURS	5	7	10	12	14	All waking hours

DO NOT wear lenses overnight or while sleeping.

FREQUENT / PLANNED REPLACEMENT

In a planned replacement program, the replacement schedule is determined by the eye care professional based upon the patient's physiological condition. PEGAVISION contact lens recommends the following replacement schedule for these lenses when prescribed in a Planned Replacement Program: (The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary)

- Aquamax Monthly Disposable Soft Contact Lenses: Replace Every 4 weeks

Wearing schedules (NOTE SEE WEARING TIME)

Daily Wear Contact Lens	Water Content	Disposable program	UV block	Wear
Aquamax Monthly Disposable Soft Contact Lens	58%	4 weeks	Yes	Daily

LENS CARE DIRECTIONS

- Daily** lenses are discarded upon removal from the eye **each day**.
- Daily** Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available. (See BASIC INSTRUCTIONS FOR LENS CLEANING, RINSING AND DISINFECTION below.)

Planned Replacement:

Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the package inserts and patient instructions provided with the lens care products recommended by the eye care professional. Failure to follow the complete regimen in accordance with manufacturer's package inserts and patient instructions may contribute to problems and/or result in the development of serious ocular complications as discussed in WARNINGS

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: LENS CARE PRECAUTION and Basic Instruction.

LENS CARE PRECAUTION

The following solutions are recommended lens care solution for use with PEGAVISION Contact Lenses. Eye care Practitioners should review with the patient lens care directions, including both basic lens care information and specific instruction on the lens care regimen recommended for the patient.

Basic Instructions For Lens Cleaning, Rinsing and Disinfection:

Care of contact lenses takes very little time to keep your eyes health.

- When lenses are dispensed, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.
- Note: Some solutions may have more than one function, which would be indicated on the label. Read the label on the solution bottle, and follow instructions.
- 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, and 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 the manufacturer and/or the eye care practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals.
- Eye care practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.
- Lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by the practitioner. (see indications)

Many solutions are now multipurpose and can be used to clean, rinse and disinfect as indicated by the instructions and the labeling. To help avoid serious eye injury from contamination:

- Always wash, rinse and dry hands before handling the lenses.
- Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.
- Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.
- Do not reuse solutions.
- Use only fresh solutions for each lens care step.
- Never add fresh solution to old solution in the lens

case.

- Always empty and rinse the lens case with fresh sterile rinsing or disinfecting solution and allow to air dry. At the next use of the lens case, fill with fresh sterile solution.
- Replace the lens case at regular intervals to help prevent case contamination by microorganisms which can cause eye infection.
- Do not alternate or mix lens care systems unless indicated on solution labeling.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.
- Always use fresh unexpired lens care solutions.
- 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 and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

Chemical (Not Heat) Disinfection:

- Wash and rinse your hands thoroughly BEFORE HANDLING LENS.
- After removal of lens, CLEAN the lens by applying three drops of cleaner to each surface. Then rub the lens between your fingers for 20 seconds.
- AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
- Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells and soak as recommend in solution labeling.
- 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 care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses must be ineffective 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.
- Put 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 on the eye should reduce the potential for irritation.

Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria growth. After removing the lens from the case, empty and rinse the lens storage case with solution as recommended by the lens case manufacture; then allow the lens case to air dry. When the case is reused again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacture or your eye care practitioner

Lens Care Regimen:

Patients must adhere to the lens care regimen recommended by their eye care practitioner for the PEGAVISION contact Lens. Failure to follow this procedure may result in development of serious ocular infections.

(Note not for daily lenses)

Lens Deposits and Use of Enzymatic Cleaning Procedure:

Enzyme cleaning may be recommended by the 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 health 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.

Care for A Dried Out (Dehydrated) or Dry Lens:

If a soft, hydrophilic contact 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, such as a counter top, apply saline or rinsing solution before handling.

To re-hydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and immerse the lens in a recommended rinsing and storing solution for at least two hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after immersion, the lens does not become soft, the lens should not be used until examined by the eye care practitioner.

Warning:

If disposable lens dry out completely, please discard

immediately.

Care for A Sticking (Nonmoving) Lens:

If the lens sticks (cannot be moved), you should be instructed to use a lubricating or rewetting solution in your eye. You should apply 3 to 4 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 15 minutes, you should IMMEDIATELY consult your eye care practitioner.

- All lenses that have been opened must be disinfected after each fitting and at least once each week. Unopened lenses are sterile and need not be disinfected until the blister pack seal has been broken.
- The PEGAVISION contact lens must be stored only in the recommended solution.
- Always keep your lens completely immersed in a recommended disinfecting/conditioning solution when the lenses are not being worn.
- If the lens dehydrates reference the above section on care for a dried out (dehydrated) OR dry lens.

Storage:

- Storage and transport of product in room temperature.
- Please keep at room temperature to avoid exposure to sunlight.
- If the lens is accidentally stored over the storage temperature (15~25 °C), such as in the car at noon on summer or freezing, short-term storage temperature does not affect the lens function and aseptic packaging, but does not mean that it can exceed the storage temperature for several weeks or several months. If there is over the storage temperature, please use these lenses first. Please return to room temperature before opening the sterile package, and confirm whether the aseptic package leaks. If it leaks, please discard the lens and avoid using it.

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 THEN REMOVE LENSES PROMPTLY. CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each PEGAVISION Contact Lens is marked with the manufacturing lot number of the lens, the base curve, sphere power, cylinder power, axis, diameter, and expiration date on the container.

PEGAVISION Corp



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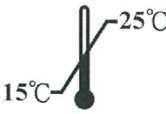


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Attn:



SYMBOL	DESCRIPTION
	Product certification Notify Body number: 2460
	See Instruction Leaflet
	Batch code
	Sterilized Using Steam
	Use by Expressed as: CCYY-MM- or CCYY-MM-DD YYYY-MM
	CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.
	Consult instructions for use
	Do not use if package is damaged
	UV-Blocking (The mark is showing functional of UV blocking, it's just reminding symbol.)
C.T.	Center thickness (product property)
D	Diopter (Lens Power)(product property)

SYMBOL	DESCRIPTION
	property)
BC	Base Curve (product property)
CYL	Cylinder Power (product property for Toric)
Axis	Axis (product property for Toric)
ADD	ADD (product property for Multifocal)
	Do not resterilize
	Authorized representative in European Community
	Manufacturer
	Temperature limit
	Lens Orientation Correct
	Lens Orientation Incorrect (Lens Inside Out)