

## Patient Instruction Booklet

For Wearers of Freshlook\*
(phemfilcon A) Soft Contact Lenses
For Daily Wear

FREQUENT REPLACEMENT WEAR PROGRAM



CAUTION: FEDERAL (UNITED STATES) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL This page intentionally left blank

#### **IMPORTANT**

This Patient Instruction Booklet contains important information and instructions about FreshLook\* (phemfilcon A) Spherical and Toric Soft (Hydrophilic) Contact Lenses for Daily Wear, including: FreshLook\* Handling Tint, FreshLook\* COLORS, FreshLook\* COLORBLENDS\*, and FreshLook\* Dimensions; FreshLook\* Toric: Handling Tint and FreshLook\* COLORBLENDS\* soft (hydrophilic) contact lenses.

# IMPORTANT: PLEASE READ CAREFULLY AND KEEP THIS INFORMATION FOR FUTURE USE

Personal Property of:			
Name:			
Street:			
City:			
Date Lenses Received:			
Eye Care Professional:			
Street:			
City:	_ State:	_ Zip:	
Telephone:			
Emergency Number:			
How Lenses are Supplied:			
Right Eye Power:			
Left Eye Power:			
Lens Color:			
Lens Replacement Schedule:			
Appointment Schedule for Check-up Exam:			
ADDITIONAL INSTRUCTIONS: _			

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#### **COMMONLY USED TERMS**

Cornea The clear "window" of the eye, permitting light to enter,

located in the front of the iris and pupil.

• Iris - The colored part of the eye which controls the

size of the pupil.

• Pupil – The black round opening surrounded by the

iris.

Sclera The white part of the eye

Dehydrate To dry out

Hydrophilic Water-loving

Saline A 0.9% solution of sodium chloride in water, similar in

many respects to human tears

The following may appear on the labels or cartons:

Symbol	Description
Rx only	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
STERILE	Steam sterilized
EXP	Use by date (Expiry date)
LOT	Batch code
en	Example of two letter language code (English)
•••	Manufacturer

Symbol	Description
EC REP	Authorized Representative European Community
DIA	Diameter
ВС	Base curve
PWR	Lens power
<b>C</b> € <sub>0086</sub>	European conformity sign
<u></u> ⚠ ☐i	See product instructions
	Packaging waste license sign

#### INTRODUCTION

Welcome to the FreshLook\* (phemfilcon A) Soft (Hydrophilic) Contact Lens family of frequent replacement contact lenses. This booklet contains instructions in the proper method of handling and caring for your FreshLook\* lenses for Frequent Replacement Wear.

In the Frequent Replacement Program, every time the lens needs to be removed before the replacement time period has elapsed, the lens must be both cleaned and disinfected prior to placing it back on the eye. CIBA VISION recommends that the lens be discarded and replaced with a new lens every 2 weeks, or as recommended by your eye care professional.

To maintain optimal eye health, it is important that you use FreshLook lenses for the wearing period prescribed by your eye care professional. Your eye care professional will prescribe a program of care based on your specific needs which includes wearing time, follow-up visits, and replacement schedules.

CIBA VISION recommends that contact lens wearers see their eye care professional at least twice each year, or if directed, more frequently.

Your eye care professional will review with you all instructions for lens handling and care, including how to properly insert and remove the lenses. At the end of your wearing regimen, which has been prescribed by your eye care professional, lenses should be removed, cleaned and disinfected prior to placing the lenses back on your eyes. If you have any questions, always ask your eye care professional.

#### **INDICATIONS (USES)**

#### **Vision Correction:**

#### **Spherical**

FreshLook\* Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for daily wear for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2.0 diopters that does not interfere with visual acuity. The FreshLook\* COLORS,

FreshLook\* COLORBLENDS\* and FreshLook\* DIMENSIONS lenses act to enhance or alter the apparent color of the eye.

#### **Toric**

FreshLook\* Toric (phemfilcon A) soft (hydrophilic) contact lenses are indicated for daily wear for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6.0 diopters. The FreshLook\* COLORBLENDS\* Toric lenses act to enhance or alter the apparent color of the eye.

The eye care professional may prescribe the lens for frequent/ planned replacement with daily removal for cleaning and disinfection. The lens may be disinfected using a chemical disinfection system. FreshLook soft contact lenses with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye. See the "WARNINGS" section with references to the relationship between lens wearing schedule and corneal complications.

#### 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 drive with monovision correction only if you pass your state driver's license

requirements with your 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 professional 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 contact lens correction to provide the clearest vision for critical tasks. You should discuss this with your eye care professional.

It is important that you follow your eye care professional'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 professional in conjunction with you, after carefully considering and discussing your needs.

#### **CONTRAINDICATIONS (REASONS NOT TO USE)**

FreshLook\* Spherical (phemfilcon A) soft (hydrophilic) contact lenses are contraindicated when any of the following conditions exist:

- Inflammation or infection in or around the eye or eyelids.
- Active disease, injury or abnormality affecting the cornea, conjunctiva or eyelids.
- Insufficiency of lacrimal secretion (dry eyes).
- Any condition which reduces corneal sensitivity.
- Use of medication that is contraindicated, including eye medications.
- Patient history of recurring eye or eyelid infections, including sties, or of adverse effects associated with

- contact lens wear or of intolerance of abnormal ocular response to contact lens wear.
- Patients who are non-compliant with contact lens care and disinfection regimens, wearing restrictions, wearing schedule or follow-up visit schedule.
- Allergy to any ingredient such as mercury or thimerosal in a solution which must be used to care for the lens.
- Patients who would not, or could not, adhere to a recommended care system for lenses, or who are unable to place and remove lenses should not be provided with them.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- If eyes become red or irritated.

#### **WARNINGS**

Prior to purchasing contact lenses, you should discuss fully with your eye care professional the effect of contact lenses on your eyes, and all risks associated with contact lens wear, in addition to receiving a thorough eye examination.

While the great majority of people successfully wear contact lenses without problems, a small percentage of wearers have experienced adverse effects with contact lens wear and usage of lens care solutions resulting in serious eye problems such as infections, ulcers, and other damage to the cornea (the front layer of the eye). In some cases, these problems can lead to serious eye injury and loss of vision, particularly if prompt and effective medical treatment is not obtained. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.

To minimize the risk of contact lens wear, it is essential that you follow your eye care professional's directions and all instruction in this booklet for proper care and handling of our lenses, use of solutions and other lens care products, wearing restrictions and schedule, lens replacement and check-up visits.

If a problem should occur, you may require immediate medical attention because some eye problems, such as infections and corneal ulcers, can develop rapidly and unexpectedly lead to loss of vision. Prompt professional attention to these problems is essential. If you have any pain, eye discomfort, tearing sensitivity to light, vision changes, redness of the eye or any other symptoms or unusual feeling in your eye, follow the steps in the "Adverse Effects" section.

UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV absorbing goggles or sunglasses. Persons should continue to use their protective UV absorbing eyewear as directed.

NOTE: The effectiveness of wearing UV absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV light has not been established at this time.

#### PRECAUTIONS AND WEARING RESTRICTIONS

The safe wear of contact lenses requires you to observe certain precautions and wearing restrictions designated to reduce the possibility of problems and eye injuries. Your eye care professional may prescribe additional precautions and restrictions for you to follow, and you should ask your eye care professional to explain anything that you do not understand.

#### At Your Initial Visit to Your Eye Care Professional:

- Be sure that you read and understand the full context of this booklet, and discuss it with your eye care professional.
- Give your eye care professional a complete history of your eye health, including any eye injuries, diseases, conditions, or other problems you have had with your eyes, even if they seem unimportant to you.
- Also, tell your eye care professional about your general health: any medicines you are taking, current treatment by a physician, any disease you had or now have and any prior surgery.
- Before leaving your eye care professional's office, make sure that you are able to place and promptly remove your lenses.

#### **Lens Handling**

FreshLook\* Spherical (phemfilcon A) soft (hydrophilic) contact lenses prescribed for Frequent Replacement Wear are intended to be disposed of at the end of the prescribed period (1 week, 2 weeks, etc.). Therefore, it is important to always have available a pair of new sterile replacement lenses. In the event that a lens must be removed from your eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated (dry), the lens should be removed, cleaned and disinfected before reinsertion. If new sterile replacement lenses are not available, the lenses should be cleaned and disinfected per the "Emergency Lens Care Directions" section. If the lens becomes dehydrated, refer to the "Care for a Dehydrated Lens" section.

- Do not touch your eyes or contact lenses until after you have washed, rinsed and dried your hands thoroughly.
   Failure to wash your hands before handling may result in eye infections.
- Do not allow any cosmetics, lotions, soaps, creams or deodorants to come in contact with lenses, which also can cause eye infections or irritations.
- Do not touch lenses with your fingernail, which can cause lens contamination or damage of the lens. If a lens becomes nicked or torn, do not wear it because damaged lenses can cause injury.
- Before placing lenses on your eyes, examine the lenses to assure they are moist, clean, clear and free of any nicks or tears.
- Do not place a dry or brittle lens on your eye.
- Do not use saliva, tap water, distilled water or anything other than a recommended sterile solution labeled for the care of your soft lenses.
- Do not use tweezers or other tools to remove your lens from the lens package. Pour the lens into your hand.
- Soft contact lenses occasionally fold on the eye and do

not remain on the cornea (front portion). This is no cause for alarm. Although the contact lens can never be lost behind the eye, it may become lodged under the eyelids without irritation (usually the upper lid). In this case, the lens should be located and removed by yourself or, if you cannot find it, by your eye care professional. Once removed, dispose of the lens and replace it with a new lens.

• It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution or drops recommended by your eye care professional into your eye. Do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of solution or drops, contact your eye care professional immediately.

#### **Wearing Restrictions:**

- Always keep a pair of new sterile replacement lenses with you when you wear your lenses, in case you have to remove the lenses immediately upon the appearance of a problem or symptom.
- Do not use aerosol products, such as hair spray, while wearing your lenses. The lenses may absorb the spray resulting in injury to the eye and damage to the lenses.
- Avoid wearing lenses around fumes, irritating vapors, smoky or dusty conditions. The lenses may absorb the chemicals or particles, resulting in injury to the eye.
- Avoid rubbing your eyes with the lenses in, which can irritate the eye or dislodge the lens.
- Keep your eyes closed tightly when washing or showering to keep water and soap out of the eyes, which can cause loss of the lenses, contamination or injury to the eye.
- Do not wear your lenses while in a hot tub, steam room,

water skiing, or swimming. Exposure to water while wearing contact lenses may increase the risk of eye infection.

- If you get something in your eye, the lens must be removed from the eye because of dust, a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry), the lens should be removed, cleaned and disinfected before reinsertion. Do not replace the lens until your eye feels normal.
- Tell your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or that you not wear contact lenses.
- Tell your regular physician and every other doctor that you visit that you wear contact lenses and the type of lenses that you wear. If you are admitted to a hospital, also tell your nurses that you wear contact lenses.
- Do not use any eye drops, ointments or medicines in your eye unless they are specifically approved by your eye care professional or physician. Some drops, ointments or medicines will cause injury to the eye if used by a contact lens wearer.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses.
   Patients should be cautioned accordingly.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness may cause dryness of the eye, increased lens awareness or blurred vision.
   Should these conditions exist, proper remedial measures should be prescribed. Depending on the severity, this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used.
- Do not share your lenses with anyone as this may spread microorganisms which could result in serious eye health

problems.

 Cosmetically tinted contact lenses may cause reduced visibility in low light conditions. Do not sleep with the lenses on. If you forget, however, check to see immediately upon awakening if the lenses will move on the eyes. If they do not move readily, do not attempt to remove them. Place several drops of the recommended lubricating or rewetting solution in the eyes and try moving them again. If, after several applications of solution, the lenses still do not move, contact your eye care professional immediately.

#### On Check-Up Visits to Your Eye Care Professional

- When you return for check-up visits, be sure to tell your eye care professional if your eyes have felt dry, irritated or anything other than completely comfortable while wearing your contact lenses.
- If there is any question in your mind about your wearing schedule and restrictions, lens handling procedures, lens replacement program, the condition of your lenses, your follow-up visit schedule, emergency cleaning and disinfection procedures or anything else about contact lens wear, be sure to discuss the subject with your eye care professional who is there to help you use your contact lenses safely and properly. The use of most dyes and drops will require a waiting period before new lenses may be inserted.

#### **BEFORE HANDLING LENSES**

It is essential to follow good practices in the care and handling of your lenses. Get into the habit of using proper procedures every time so that they become automatic. Cleanliness is the first and most important principle of proper contact lens care. Before touching lenses, always wash hands with neutral un-medicated soap, rinse thoroughly, and dry with a lint-free towel. Avoid using oils, hand creams, lotions or any medications on hand before handling lenses. Such materials may get on lenses and interfere with successful wear. Make certain your fingernails are well trimmed and smooth so they do not damage lenses.

#### CARE FOR DEHYDRATED LENS

If a 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 sterile saline solution before handling.

Please note the following:

- Handle the lens carefully.
- Place the lens in a 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 and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, it should not be worn until examined by your eye care professional.

#### THE LENS PACKAGE

Your lens prescription may not be the same for both eyes, so it is important that your eye care professional tell you which lenses are for your right eye, and which lenses are for your left. You should indicate in the space given on the box whether the lenses are for right or left eyes.

#### **OPENING THE LENS PACKAGE**

To open the lens package, first shake the lens package to correctly position the lens in the solution. Place the lens package on a flat surface, then slowly and carefully peel back the foil where indicated on the label.

#### PREPARING LENS FOR WEAR

- 1. Carefully remove the right lens from the plastic package. Avoid mix-ups; work with one lens at a time. Get in the habit of starting with the right lens.
- To correctly position the lens for insertion, place the lens on the tip of a finger. When looking down upon the lens, an "FL" or "FTL" logo should be seen at the bottom edge of the

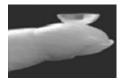
lens. If the FL or FTL logo is inverted, then the lens is inverted.

#### **LENS INSERTION**

Fingers should never touch the eye during lens insertion or removal. Two lens insertion methods, A and B are described; use the one most comfortable for you.

#### METHOD A - One Hand Method

1. Place right lens on index finger of dominant hand.



2. Hold down lower lid with middle finger of dominant hand and look up.



- 3. Place lens on lower portion of the white part of the eye. Apply gentle pressure to expel any air under lens. Use of a mirror may help place the lens correctly.
- 4. Continue to hold lens against eye while releasing the lower lid.
- 5. Look down and remove finger from lens. Lens should immediately center

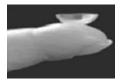
6. To help center lens, close eye momentarily and lightly massage the closed lid. It may take a few minutes for the lens to center



7. Insert left lens following the same procedure.

#### **METHOD B** - Two Hand Method

1. Place right lens on index finger of dominant hand.



- 2. Hold down lower lid with middle finger of dominant hand
- 3. With your other hand, use the fingers to lift the upper eyelid.



- 4. While looking in a mirror or straight ahead, gently place lens on eye.
- 5. Slowly release lids then blink. Lens should immediately center.
- 6. To help center lens, close eye and lightly massage lid.



7. Insert left lens following the same procedure.

Within a very brief time after insertion, lenses should be comfortable and vision should be clear. If non-movement of the lens continues after several minutes, you should immediately consult your eye care practitioner.

Any discomfort may be caused by the presence of a foreign body or incorrect insertion. Poor vision may be caused by mixing right and left lenses or by a lens which has been displaced off center. If you cannot find cause and correct the situation, discontinue wear and consult your eye care professional.

#### **LENS REMOVAL**

1. Pull down lower lid with the finger of dominant hand.



2. Look up and lightly place tip of index finger of dominant hand on the lens.



3. Slowly slide lens down onto the white of eye. Keep finger on lens and compress lens between thumb and finger. Remove the lens.



4. After lens removal, follow your eye care professional's instructions for lens care and replacement.

**GENERAL TIPS** Hand must be washed, rinsed thoroughly and dried with a lint free towel before handling the lenses

Cosmetics, lotions, soaps and creams must not come in contact with the lenses since eye irritation or infection may result. Do not use aerosol or pump products, such as hair spray, while the lenses are being worn, since liquids and vapors may damage the lens. If your contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated.

Lenses must be cleaned and disinfected as often as recommended by the eye care professional. Use a suggested chemical (not heat) system of lens care since heat may cause discoloration. Use and follow instructions of lens care

products intended for use with soft (hydrophilic) contact lenses recommended by your eye care professional.

#### **ADVERSE EFFECTS (POSSIBLE PROBLEMS)**

#### **Problems and What to Do**

The following problems may occur:

- Eye discomfort.
- Eye pain.
- Eye sting, burn or itch (irritation).
- Comfort is less than when lens was first placed on the eye. Feeling of something in eye (foreign body, scratched area).
- Watering (tearing) of eyes.
- Eye secretions or discharge of matter. Redness of the eyes.
- Reduced sharpness or decrease in vision.
- Blurred vision, rainbows or halos around objects.
- Sensitivity to light.
- Feeling of dryness.

If any of the above symptoms occur:

IMMEDIATELY remove the lens(es). If the discomfort or problem stops, then look closely at the lens(es).

- o If the lens(es) is in any way damaged, DO NOT put the lens back in the eye. Discard the lens.
- o If the lens has dirt, an eyelash, or other foreign body on it, thoroughly clean, rinse, and disinfect prior to reinsertion.

If the above symptoms continue after removal of the lens or upon insertion of a new lens, remove the lens immediately and you should contact your eye care professional or a physician who will determine the need for examination, treatment or referral without delay.

#### **Chemicals in Eyes**

If chemicals of any kind (household products, gardening solutions or laboratory chemicals) are splashed into the eyes, do the following:

- Immediately remove your lenses and flush your eyes with water.
- If unable to remove lenses, immediately flush your eyes with water.
- Seek immediate medical eye care treatment.

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

#### IF IN DOUBT, TAKE THE LENS OUT!

Problems with contact lenses may lead to a medical emergency because a serious condition such as an infection, corneal ulcer, neovascularization (small blood vessels growing into the cornea), or iritis (inflammation of the eye) may be present, and may progress rapidly and lead to loss of vision unless treated promptly. When you go for treatment, bring your lenses, lens case and care products. The doctor may want to examine, test or even analyze these items to help in your treatment. If your eye care professional or physician is not available, go to the nearest emergency room.

The safe wear of contact lenses requires you to observe certain precautions and wearing restrictions designed to reduce the possibility of problems and eye injuries. Your eye care professional may prescribe additional precautions and restrictions for you to follow, and you should ask your eye care professional to explain anything that you do not understand.

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