

Fanfilcon A

**Fanfilcon A Sphere
Fanfilcon A Asphere
Fanfilcon A Toric
Fanfilcon A Multifocal
Fanfilcon A Multifocal Toric**

DAILY WEAR

SOFT (HYDROPHILIC) CONTACT LENSES

PATIENT INFORMATION BOOKLET

IMPORTANT: This Patient Information Booklet contains important information and instructions. Please read carefully and keep this information for future use.

TABLE OF CONTENTS

| | |
|---|----|
| 1. INTRODUCTION..... | 3 |
| 1.1. BENEFITS..... | 3 |
| 1.2. RISKS..... | 3 |
| 2. WEARING RESTRICTIONS AND INDICATIONS..... | 4 |
| 3. CONTRAINDICATIONS (REASONS NOT TO USE)..... | 4 |
| 4. WARNINGS..... | 5 |
| 5. PRECAUTIONS..... | 5 |
| 6. ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):..... | 6 |
| 7. INSTRUCTIONS FOR LENS HANDLING..... | 7 |
| 7.1. PREPARING THE LENS FOR WEARING..... | 7 |
| 7.2. LENS PACKAGE..... | 7 |
| 7.3. HANDLING THE LENSES..... | 8 |
| 7.4. PLACING THE LENS ON THE EYE..... | 8 |
| 7.5. CENTERING THE LENS..... | 9 |
| 7.6. REMOVING THE LENS..... | 10 |
| 8. CARING FOR YOUR LENSES WHEN PRESCRIBED FOR FREQUENT REPLACEMENT..... | 11 |
| 8.1. INSTRUCTIONS (CLEANING, RINSING, DISINFECTING, STORAGE AND REWETTING / LUBRICATING)..... | 11 |
| 8.2. CARE FOR A STICKING (NON-MOVING) LENS..... | 13 |
| 8.3. CARE FOR A DEHYDRATED LENS..... | 13 |
| 8.4. EMERGENCIES..... | 13 |
| 9. INSTRUCTIONS FOR THE PRESBYOPIC WEARER..... | 14 |
| 10. POSSIBLE FAILURE MODES/TROUBLESHOOTING..... | 15 |
| 11. WEARING AND APPOINTMENT SCHEDULES..... | 16 |
| 12. EYE CARE PRACTITIONER INFORMATION..... | 17 |
| 13. GLOSSARY OF TECHNICAL TERMS..... | 18 |
| 14. PACKAGE INSERT..... | 19 |

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale on or by the Order of a Licensed Practitioner

1. INTRODUCTION

The fanfilcon A Soft (hydrophilic) Contact Lenses are soft lenses. They are made from a "water-loving" (hydrophilic) material that has the ability to absorb water, making the lens soft and flexible.

The fanfilcon A soft (hydrophilic) lenses are indicated for daily wear. If prescribed for frequent replacement, your prescriber should recommend a care system that is appropriate for your lens. Carefully read and follow specific directions for use and important safety information for each lens care product. Discard the lens if the lens becomes damaged or you reach the prescribed wearing period recommended by your Eye Care Practitioner. You should always have replacement lenses or glasses available. If prescribed for single-use disposable wear, the fanfilcon A soft contact lens is to be discarded after each removal.

The information and instructions contained in this booklet apply only to the fanfilcon A sphere, asphere, toric, multifocal and multifocal toric soft (hydrophilic) contact lens, referred to as your contact lenses. For your eye health, it is important to wear your lenses as prescribed by your Eye Care Practitioner. It is also important to keep your Eye Care Practitioner fully aware of your medical history. Your Eye Care Practitioner will tailor a total program of care based on your specific needs. He or she will review with you all instructions for lens handling, including how to safely and easily open the package. You will receive instruction on how to properly insert and remove lenses. This booklet will reinforce those instructions. Discard and replace your contact lenses with a new sterile pair, as prescribed by your Eye Care Practitioner.

Please refer to the Section 13, GLOSSARY OF TECHNICAL TERMS, for definitions of medical/technical terms used in this booklet.

1.1. Benefits¹

Contact lenses provide vision correction.

If you lead an active lifestyle, contacts can provide:

- close to natural vision
- excellent peripheral vision for sports and driving.
- advantages for athletes and those with an active lifestyle

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

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

1.2. Risks²

Wearing contact lenses puts you at risk of several serious conditions including eye infections and corneal ulcers. These conditions can develop very quickly and can be very serious. In rare cases, these conditions can cause blindness. Other risks of contact lenses include pink eye (conjunctivitis), corneal abrasions and eye irritation. For further detail, see Section 4, WARNINGS, and Section 6, ADVERSE REACTIONS.

¹ Contact Lens Comfort ,Contact Lens Council, <http://www.contactlenscouncil.org/scon-comfort.htm>

² US FDA CDRH Contact Lens Risks Page, <http://www.fda.gov/cdrh/contactlenses/risks.html>

2. WEARING RESTRICTIONS AND INDICATIONS

Sphere/Asphere: Fanfilcon A SPHERE and fanfilcon A ASPHERE Soft Contact Lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

Toric: Fanfilcon A TORIC Soft Contact Lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

Multifocal: Fanfilcon A MULTIFOCAL Soft Contact Lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric: Fanfilcon A MULTIFOCAL TORIC Soft Contact Lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -10.00 diopters.

Eye Care Practitioners may prescribe the fanfilcon A Soft Contact Lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for single-use disposable wear.

When prescribed for frequent/planned replacement, the fanfilcon A Soft Contact Lens is to be cleaned, rinsed, and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Practitioner. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.

When prescribed for single-use disposable wear, the fanfilcon A Soft Contact Lens is to be discarded after each removal.

3. CONTRAINDICATIONS (REASONS NOT TO USE)

Do not use your 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 dry eye.
- Reduced corneal sensitivity (corneal hypoesthesia).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses. For example, Sjogren's syndrome, rheumatoid arthritis, lupus and collagen vascular diseases affect your ability to wear contact lenses.
- Allergic reactions of ocular surfaces or surrounding tissues (adnexa) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- An allergic reaction can occur to any ingredient in contact lens solutions. Example: some people are allergic to the trace amounts of mercury or thimerosal included as active ingredient in some contact lens solutions.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- If you are unable to follow lens care regimen or unable to obtain assistance to do so.

4. WARNINGS

What You Should Know About Contact Lens Wear:

UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and the surrounding area. You should continue to use UV-absorbing eyewear as directed.

Long term exposure to the UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of the outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your Eye Care Practitioner for more information.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow Eye Care Practitioner's directions and all labeling instructions for proper use of lenses. 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 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.

The results of a study³ indicate the following:

- a. The overall annual incidence of infected corneal ulcer (ulcerative keratitis) in daily wear contact lens users is estimated to be about 4.1 per 10,000 persons and about 20.9 per 10,000 persons in extended wear contact lens users.
- b. The risk of infected corneal ulcer (ulcerative keratitis) is 4 to 5 times greater for extended wear contact lens users than for daily wear users. When daily wear users who wear their lenses overnight and extended wear users who wear their lenses on a daily basis are excluded from the comparison, the risk among extended wear users are 10 to 15 times greater than among daily wear users.
- c. When daily users wear their lenses overnight (outside the approved indication), the risk of ulcerative keratitis is 9 times greater than among those who do not wear them overnight.
- d. The overall risk of infected corneal ulcer (ulcerative keratitis) may be reduced by carefully following directions for lens care, including cleaning the lens case.
- e. The risk of infected corneal ulcer (ulcerative keratitis) among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.
- f. If you experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, you should be instructed to immediately remove your lenses and promptly contact your Eye Care Practitioner. It is recommended that you see your Eye Care Practitioner routinely as directed.

5. PRECAUTIONS

Handling Precautions:

- Do not use if the sterile blister package is opened or damaged.

³ New England Journal of Medicine, September 21, 1989;321(12),pp.773-783

- 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.
- Lens damage may occur if you handle your lens with dirty hands.
- Carefully follow the handling, insertion, removal, cleaning, and wearing instructions prescribed by your Eye Care Practitioner.
- Always handle lenses gently and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container. Pour the lens and packaging solution into your hand.
- Do not touch the lens with fingernails.

Lens Wearing Precautions:

- Never wear your lenses beyond the period recommended by your Eye Care Practitioner.
- If aerosol products such as hairspray are used while wearing lenses, be careful and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask your Eye Care Practitioner about wearing the lenses during sporting activities.
- Always discard lenses following the recommended replacement schedule prescribed by your Eye Care Practitioner.

Who Should Know That You are Wearing Contact Lenses:

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

Multifocal or monovision contact lens wear:

- Some patients who wear multifocal or monovision contact lenses may not be able to get the best corrected visual acuity for either far or near vision. Your Eye Care Practitioner should work with you to select the most appropriate type of lens for your needs.

Other Topics to Discuss with Your Eye Care Practitioner:

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

6. ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO):

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

- Your eyes may burn, sting and/or itch or you may experience other eye pain.
- Comfort may be less than when the lens was first placed on the eye.
- There may be a feeling that something is in the eye such as a foreign body or a scratched area.
- There may be excessive watering (tearing), unusual eye secretions or redness of your eye.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects, sensitivity to light (photophobia) or dry eyes may also occur if your lenses are worn continuously or for too long a time.

If you notice any of the above, you should:

- **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 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. Once this is done, you should reinsert them.

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

7. INSTRUCTIONS FOR LENS HANDLING

7.1. 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. These substances may contact the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips. Be careful to avoid touching the lens with fingernails. It is helpful to keep your fingernails short and smooth.

Start correctly; always use proper hygienic procedures.

7.2. Lens Package

The individual package is designed specifically to maintain sterility. The lens packages are individual.

To open an individual lens package, follow these simple steps:

- Shake the lens package and check to see that the lens is floating in the solution.
- Peel back the foil closure to reveal the lens. Stabilizing the lens package on the tabletop, will minimize the possibility of a sudden splash.

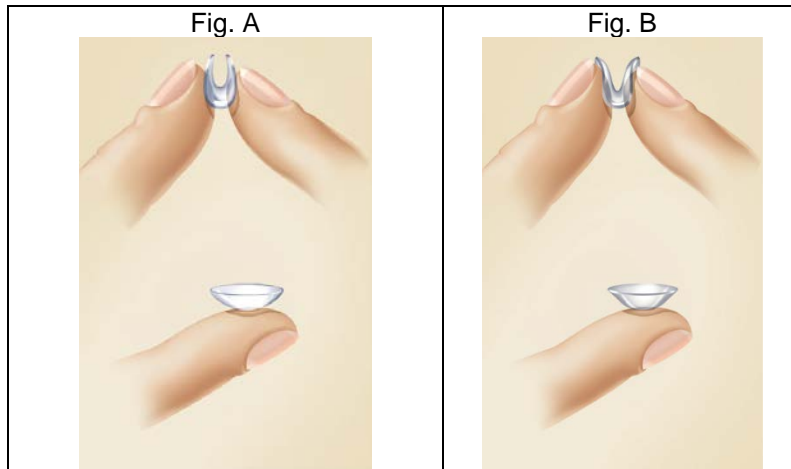
Occasionally on opening, a lens may adhere to the inside surface of the foil, or to the plastic package itself. This will not affect the sterility of the lens. It is still perfectly safe to use. Carefully remove and inspect the lens following the handling instructions.

7.3. Handling the Lenses

- Develop the habit of always working with the right lens first to avoid mix-ups.
- Remove the right lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears. If the lens appears damaged, do not use it. Use a new lens.

Verify that the lens is not turned inside out by placing it on your forefinger and checking its profile. The lens should assume a natural, curved, bowl-like shape (Fig. A). If the lens edges tend to point outward, the lens is inside out (Fig. B).

Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward (Fig A). If the lens is inside out, the edges will turn slightly outward (Fig. B).



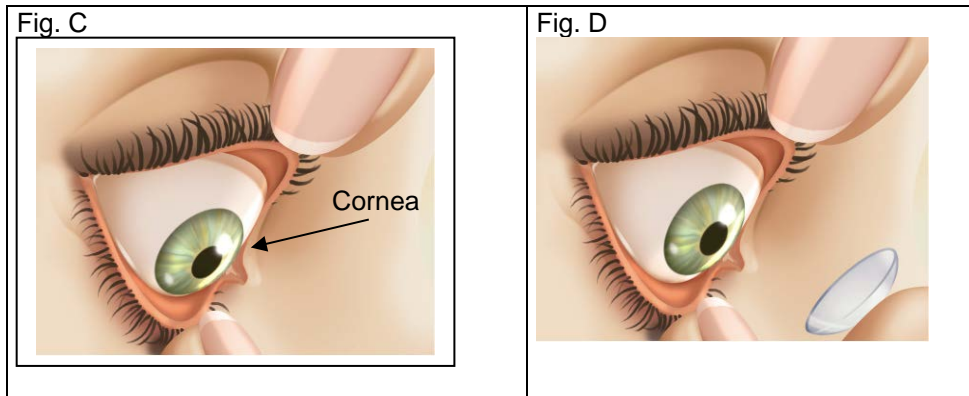
7.4. Placing the Lens on the Eye

Start with your right eye.

Once you have opened the lens package and removed and examined the lens, follow these steps to apply the lens to your eye:

- a. Place the lens on the tip of your forefinger. **BE SURE THE LENS IS CORRECTLY ORIENTED** (see Section 7.3 "Handling the Lenses").
- b. Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid (Fig. C).
- c. Use the forefinger or middle finger of the other hand to lift the upper lid.
- d. Place the lens on the eye (Fig. D).
- e. Gently release the lids and blink. The lens will center automatically.
- f. Use the same technique when inserting the lens for your left 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 Section 7.5 "Centering the Lens").
- If the lens is centered, remove the lens (see Section 7.6 "Removing the Lens") and check for the following:
 - a. Cosmetics or oils on the lens. Clean the lens.
 - b. The lens is on the wrong eye.
 - c. The lens is inside out (it would also not be as comfortable as normal).

If you find your vision remains blurred, after checking the above possibilities, remove both lenses and consult your Eye Care Practitioner.

After you have successfully inserted your lenses, you should ask yourself:

- How do the lenses feel in my eye?
- How do my eyes look?
- Do I see well?

If your examination shows any problems **IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PRACTITIONER.**

7.5. Centering the Lens

A lens on the cornea (center of your eye), will rarely be displaced onto the white part of the eye during wear. This can occur if insertion or removal procedures are not properly performed. To center a lens, follow either of these procedures:

- a. Close your eyelids and gently massage the lens into place through the closed lids

OR

- b. Gently manipulate the off-centered lens onto the cornea while the eye is open, using finger pressure on the edge of the upper lid or lower lid.

7.6. Removing the Lens

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

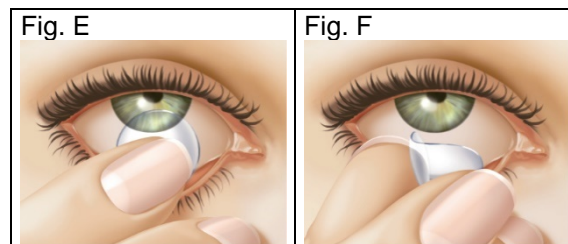
- a. Wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- b. Remove the right lens first. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that your Eye Care Practitioner recommends.

Pinch Method for removing lens:

Step 1. Look up and slide the lens to the lower part of the eye using the forefinger (Fig. E).

Step 2. Gently pinch the lens between the thumb and forefinger (Fig. F)

Step 3. Remove the lens.



Forefinger and Thumb Method for removing lens:

Step 1. Place your hand or a towel under your eye to catch the lens.

Step 2. Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.

Step 3. Press in and force a blink. The lens should fall onto your hand.

Once you remove the lens, simply follow the lens care directions recommended by the Eye Care Practitioner.

Note: The lens may come out but remain on the eyelid, finger or thumb.

- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care directions.

Note: If these methods of removing your lenses are difficult for you, your Eye Care Practitioner will show you with an alternate method.

8. CARING FOR YOUR LENSES WHEN PRESCRIBED FOR FREQUENT REPLACEMENT

8.1. Instructions (Cleaning, Rinsing, Disinfecting, Storage and Rewetting / Lubricating)

The ideal time to clean your lenses is immediately after removing them. Disinfecting is necessary to destroy harmful germs. For continued safe and comfortable wearing of your lenses, it is important that you first clean and rinse, then disinfect your lenses after each removal. Use the care regimen recommended by your Eye Care Practitioner. Cleaning and rinsing are necessary to remove mucus, secretions, films or deposits that may have accumulated during wearing.

You should adhere to recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications, as discussed in Section 4, WARNINGS.

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

Your practitioner will provide you with instructions and warnings for lens care, handling, cleaning and disinfection. Your Eye Care Practitioner should instruct you about appropriate procedures and products for your use.

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

- Always wash your hands thoroughly with a mild soap. Rinse completely. Dry 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. These substances may contact the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips. Be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.
- Always use fresh unexpired lens care solution. Do not add or “top-off” solution left in your lens case since solution reuse reduces effective lens disinfection.
- Use the recommended system of lens care (chemical not heat). Carefully follow instructions on solution labeling. Different solutions cannot always be used together. Not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems.**
- Always remove, clean, rinse and disinfect your lenses according to the schedule prescribed by your Eye Care Practitioner.
- The use of 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.
- Lenses should be thrown away after the recommended wearing period prescribed by your Eye Care Practitioner.
- 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 your lens down the drain.
- Since the lens material contains silicone, the ability of the lens to remain soft and flexible (wettability) may differ when different lens care products are used. Your Eye Care Practitioner should recommend a care system that is appropriate for you. Each lens care

product contains specific directions for use and important safety information, which you should read and carefully follow.

Note: Some solutions may have more than one function. The function of the solution is on the solution label. Read the label on the solution bottle and follow instructions.

Cleaning

- Always clean the right lens first (to avoid mix-ups). **Rinse** the lens thoroughly with recommended saline or disinfecting solution. Rinsing step helps 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.
- Follow the instructions provided in the cleaning solution labeling.

Disinfecting (Chemical-Not Heat)

- When using hydrogen peroxide lens care systems, the patient must **use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.
- Your contact lenses cannot be heat (thermally) disinfected.
- **After cleaning**, disinfect lenses using the system recommended by your Eye Care Practitioner. Follow the instructions provided in the disinfection solution labeling.
- Hydrogen peroxide lens care systems **require neutralization.** Follow the recommendations on the hydrogen peroxide system labeling.
- Leave the lenses in the unopened storage case until ready to put on the eyes.

Caution: Chemically disinfected lenses may absorb ingredients from the disinfecting solution that may be irritating to the eyes. A thorough rinse in fresh sterile saline (or another recommended solution) prior to placement on the eye may reduce the potential for irritation.

Rinsing

- Rinse before insertion of disinfected lenses.
- Thoroughly rinse lenses with fresh solution recommended for rinsing before inserting and wearing lenses. Follow the instructions on the disinfection solution labeling.

Storage

- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear.
- If you do not wear your lenses immediately following disinfection, you should consult the solution package insert or your Eye Care Practitioner for information on storage of your lenses.
- Always keep your lenses completely immersed in a recommended disinfecting solution when you are not wearing your lenses.

Care of Lens Case

- After removing your lenses from the lens case, you should clean and rinse your lens case between uses as recommended by your Eye Care Practitioner. Allow the lens case to air dry. When reusing the case, refill it with fresh solution.
- Contact lens cases can be a source of bacteria growth. Replace your lens case at regular intervals, as recommended by the lens case manufacturer or your Eye Care Practitioner.

Lubricating/Rewetting

Your Eye Care Practitioner may recommend a lubrication or rewetting solution for your use. These solutions can be used to wet (lubricate) your lenses while you are wearing them to make lens wear more comfortable.

8.2. Care for a Sticking (Non-moving) Lens

If a lens sticks (stops moving) on your eye, apply a few drops of the recommended lubricating solution. You should wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should **IMMEDIATELY** consult your Eye Care Practitioner.

8.3. Care for a Dehydrated Lens

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle. If this happens, dispose of the lens and use a fresh new one.

8.4. Emergencies

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes: **FLUSH EYES IMMEDIATELY WITH WATER AND IMMEDIATELY CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

9. INSTRUCTIONS FOR THE PRESBYOPIC WEARER

Presbyopia occurs as part of the natural aging process. The eye's crystalline lens loses its ability to bring close objects into clear focus.

Multifocal lenses, such as fanfilcon A Multifocal and Multifocal Toric lenses for astigmatism, correct presbyopia by providing distance and near vision correction powers within the same lens.

Alternatively, **monovision** is a treatment technique often prescribed for people age 40 and over who have presbyopia. Monovision means wearing a contact lens for near vision on one eye and, if needed, a lens for distance vision on the other eye. (Ref: American Optometric Association)

- The decision to be fit with a multifocal or monovision contact lenses is made by careful consideration and discussion of your needs with your Eye Care Practitioner.
- As with any type of vision correction, you should be aware that there are advantages and tradeoffs with multifocal or monovision contact lens correction. The benefit of clear near vision in straight ahead and upward gaze that is available may be accompanied by a reduction in your visual acuity and depth perception for distance and near tasks. Some patients experience difficulty adapting to multifocal or monovision contact lenses. 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 multifocal or monovision lens wear. It is recommended that you only drive with multifocal or monovision correction if you pass your state driver's license requirements with these lenses.
- Some patients will never be fully comfortable functioning under low levels of lighting, 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 optimally for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may need to wear spectacles over your lenses or have additional contact lenses prescribed specifically for this task so that both eyes are corrected for near when sharp near binocular vision is required.
- Some patients may require supplemental glasses to wear over their multifocal or 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 multifocal or monovision contact lens therapy. During the adaptation period you should make careful note of any specific situation where you feel unable to function effectively and safely and discuss any concerns that you may have during and after the adaptation period.

10. POSSIBLE FAILURE MODES/TROUBLESHOOTING

| Failure mode | Cause | Effect on patient | Remedy |
|----------------------------------|---|--|--|
| Non Centered Lens | Displacement from rubbing of eye, improper insertion or removal | Uncomfortable and blurry vision | See below "Remedy for a Non Centered Lens" |
| Sticking Lens | Inadequate blinking | Discomfort | See below "Remedy for a Sticking Lens" |
| Dried Lens | Lens stored without sufficient solution in lens case | Lens is not wearable. Lens is dry and brittle. | See below "Dried Lens in Case" |
| Chemical/Foreign Objects in Lens | Accidentally foreign object or chemicals enter the lens | Sharp pain upon insertion | See below "Remedy for Chemical/Foreign Objects in Lens" |
| Lens Inside Out | Improper insertion | Uncomfortable or blurry vision | Remove lens, rinse off, check per 7.3 and insert per 7.4 |
| Lenses Not Clean | Cosmetics or oils on the lens | Blurry vision | Remove lens, clean, disinfect and insert |

Remedy for a Non Centered Lens

A lens, which is on the cornea (center of your eye), will very rarely be displaced onto the white part of the eye during wear. This, however, can occur if insertion and removal procedures are not performed properly. To center a lens, follow either of these procedures:

- a. Close your eyelids and gently massage the lens into place through the closed lids

OR

- b. Gently manipulate the off-centered lens onto the cornea while the eye is opened, using finger pressure on the edge of the upper lid or lower lid.

Remedy for a Sticking Lens

If a lens sticks (stops moving) on your eye, apply a few drops of the recommended lubricating solution. You should wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues, you should **IMMEDIATELY** consult your Eye Care Practitioner.

Dried Lens in Case

If exposed to air while off the eye, a soft hydrophilic contact lens may become dry and brittle. If this happens, dispose of the lens and use a fresh new one.

Remedy for Chemical/Foreign Objects in Lens

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 CONSULT YOUR EYE CARE PRACTITIONER.**

11. WEARING AND APPOINTMENT SCHEDULES

Record here the number of hours your Eye Care Practitioner recommends you wear the lenses each day during the adaption period. Typically, soft contact lens patients should be able to wear their lenses 6 hours the first day, 8 hours for the second day, 10 hours for the third day, 12 hours for the fourth day, 14 hours on the fifth day and to all waking hours on the sixth day. Build-up of wearing time is important and you must follow your Eye Care Practitioner's directions.

Prescribed Wearing Schedule for Adaptation to Contact Lenses

| Day | Wearing Time (Hours) Recommended by Eye Care Practitioner |
|-----|---|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |

Appointment Schedule

Your appointments are on: _____

(Use this space to record the days and times of your follow up appointments).

Minimum number of hours lenses to be worn at time of appointment: _____

12. EYE CARE PRACTITIONER INFORMATION

To aid your ability to reach your Eye Care Practitioner, please record the contact details below.

Doctor: _____

Address: _____

Phone: _____

Use the table below to record the number of hours you wear your lenses each day during the adaptation period.

| Day | Date | Hours Worn | Day | Date | Hours Worn |
|-----|------|------------|-----|------|------------|
| 1 | | | 8 | | |
| 2 | | | 9 | | |
| 3 | | | 10 | | |
| 4 | | | 11 | | |
| 5 | | | 12 | | |
| 6 | | | 13 | | |
| 7 | | | 14 | | |

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

Notes _____

13. GLOSSARY OF TECHNICAL TERMS

| Term | Definition |
|-------------------------|--|
| Adnexa | Tissues surrounding the eyeball. |
| Ametropia | Abnormal vision requiring correction for proper focus. |
| Anterior chamber | Fluid-filled portion of the eye between the iris and innermost corneal surface. |
| Aphakic | An eye that does not have its natural lens (example: after cataract surgery). |
| Aspherical contact lens | A lens with a curve that is not round, but has different shapes across its surface. |
| Astigmatism | A condition where the cornea is not equally curved in all parts of its surface. It is somewhat oval in shape, causing the visual image to be out of focus (blurred). |
| Conjunctiva | Transparent membrane that lines the eyelids and the white part of the eye. |
| Conjunctivitis | Inflammation of the conjunctiva. |
| Continuous Wear | Extended wear for multiple nights in a row. |
| Cornea | Clear front part of the eye that covers the iris, pupil and anterior chamber. |
| Corneal erosion | Wearing away of the surface of the cornea. |
| Corneal ulcer | A sore or lesion on the cornea |
| Disinfection | A process that kills harmful microorganisms (germs) which can cause serious eye infections |
| Extended Wear | Wearing lenses for 24 hours a day, including while sleeping |
| Hydrophilic material | “Water loving” or water absorbing substance |
| Hyperopia | Farsightedness |
| Hypoesthesia | Reduced corneal sensitivity to touch |
| Iritis | Inflammation of the interior portion of the eye that includes the iris, and results in redness, pain, blurred vision and sensitivity to light. |
| Inflammation | Swelling, redness and pain |

| | |
|------------------------|---|
| Monovision | A correction method for presbyopia (loss of reading vision) using contact lenses; one eye is fitted for distance, the other for near vision. |
| Myopia | Nearsightedness |
| Neovascularization | Blood vessels growing into the cornea |
| Phakic | An eye that has its natural lens |
| Presbyopia | Condition in which as the lenses in the eyes lose some of their elasticity, as occurs with aging, they lose some of their ability to change focus for different distances (loss of reading vision). Usually becomes significant after age 40. |
| Presbyopic | A person with Presbyopia |
| Spherical contact lens | A lens with a continuously rounded curve |
| Toric contact lens | A lens with two different optical powers at right angles to each other for the correction of astigmatism |
| Ulcerative keratitis | An infected corneal ulcer |

14. PACKAGE INSERT

For fanfilcon A SPHERE/ASPHERE, fanfilcon A TORIC, fanfilcon A MULTIFOCAL, and fanfilcon A MULTIFOCAL TORIC Soft (Hydrophilic) Contact Lens Package Insert, please reference PI01125.

NAME AND ADDRESS OF MANUFACTURER:

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

The above product information and procedures are suggested by CooperVision, Inc.; however, your Eye Care Practitioners may suggest alternative products or procedures that you should follow.