



CooperVision

**BIOFINITY® & BIOFINITY® XR SPHERE and  
BIOFINITY ENERGYS™ ASPHERE (comfilcon A)**

**BIOFINITY® Toric & BIOFINITY® XR Toric  
(comfilcon A)**

**BIOFINITY® Multifocal & BIOFINITY® XR  
Multifocal (comfilcon A)**

**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.

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

## 1. INTRODUCTION

The BIOFINITY (comfilcon 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.

When used 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.

The information and instructions contained in this booklet apply only to BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A) and BIOFINITY Toric (comfilcon A), BIOFINITY XR Toric (comfilcon A), BIOFINITY Multifocal (comfilcon A) and BIOFINITY XR Multifocal (comfilcon A) 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 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. Benefits<sup>1</sup>

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. Risks<sup>2</sup>

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.

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

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

## 2. WEARING RESTRICTIONS AND INDICATIONS

### Spherical and Aspherical

**BIOFINITY and BIOFINITY XR SPHERE and ASPHERE (comfilcon A)** 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.

**BIOFINITY ENERGYS™ Asphere (comfilcon A)** 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

**BIOFINITY TORIC (comfilcon A) and BIOFINITY XR TORIC (comfilcon A)** 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 -5.75 diopters.

### Multifocal

**BIOFINITY MULTIFOCAL (comfilcon A) and BIOFINITY XR MULTIFOCAL (comfilcon A)** 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 +0.50 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.

The **BIOFINITY (comfilcon A) Soft (Hydrophilic) Contact Lenses** have been approved for extended wear for up to 6 nights /7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Practitioner.

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

## 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

### **WARNINGS:**

### **PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.**

It is essential to follow the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case.

You should be advised of the following instructions for use and warnings pertaining to contact lens wear:

#### **i. Soaking and Storing Your Lenses**

##### ***Instruction for Use:***

Use only fresh multi-purpose (contact lens disinfecting) solution each time you soak (store) your lenses.

##### **WARNING:**

Do not reuse or “top off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness.

“Topping-Off” is the addition of fresh solution to solution that has been sitting your case.

#### **ii. Rub and Rinse Time**

##### ***Instruction for Use:***

- Rub and rinse your lenses according to the recommended lens rubbing and rinsing times in the labeling of your multi-purpose solution to adequately disinfect your lenses.

##### **WARNING:**

- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

#### **iii. Lens Case Care**

##### ***Instruction for Use:***

- Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Replace your lens case according to the directions given to you by your eye care professional or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

##### **WARNING:**

Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh multi-purpose solution so you do not contaminate your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

iv. **Water Activity**

***Instruction for Use:***

- Do not expose your contact lenses to water while you are wearing them.

**WARNING:**

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If your lenses have been submersed in water when swimming in pools, lakes or oceans, you should discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

v. **Discard Date on Multipurpose Solution Bottle**

***Instruction for Use:***

- Discard any remaining solution after the recommended time period indicated on the bottle of multi-purpose solution used for disinfecting and soaking your contact lenses.
- The Discard date refers to the time you can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

**WARNING:**

Using your multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.

To avoid contaminating your solution, DO NOT transfer to other bottles or containers.

**EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF YOU EXPERIENCE:**

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes,**
- **Loss of Vision,**
- **Eye Redness**
- **Or Other Eye Problems**

**YOU SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**

- 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.

## **What You Should Know About Contact Lens Wear:**

Proper use and care of contact lenses and lens care products, including lens cases, are essential for the safe use of these products. Follow your Eye Care Practitioner's directions and all labeling instructions for proper use of lenses and lens care products. Fill your lens case with fresh solution every time you store your lenses, and never re-use solution. Additionally, you should clean and rinse your lens case between uses as recommended by your Eye Care Practitioner. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.

The results of a study<sup>3</sup> 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.
- 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.

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

### **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 wearing schedule prescribed by your Eye Care Practitioner.

### **Solution Precautions:**

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical lens care system. Use of a heat care system can damage your contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva for lubricating or wetting lenses.
- Always keep lens completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Damaged lenses must be discarded.

### **Lens Case Precautions:**

- Bacteria can grow in contact lens cases. It is important to properly use, clean and replace your cases at regular intervals recommended by the lens case manufacturer or 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.

### **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.
- Some patients will not be able to tolerate extended wear. Eye Care Practitioners should carefully evaluate their patients for extended wear prior to prescribing and dispensing. Early and frequent follow-up examinations to determine ocular response to extended wear are elements are important at this evaluation.



## 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.

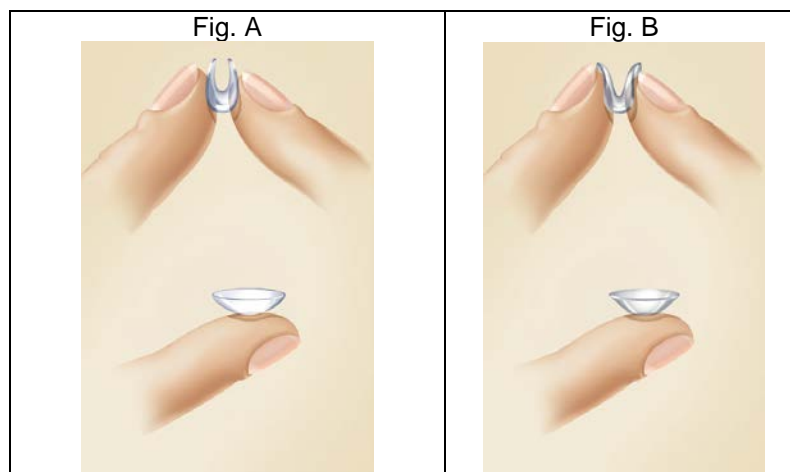
Occasionally upon opening, a lens may adhere to the inside surface of the foil or to the plastic package itself. This will not affect the sterility of the lens and it is still perfectly safe to use. Carefully remove and inspect the lens by following the handling instructions.

## 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).



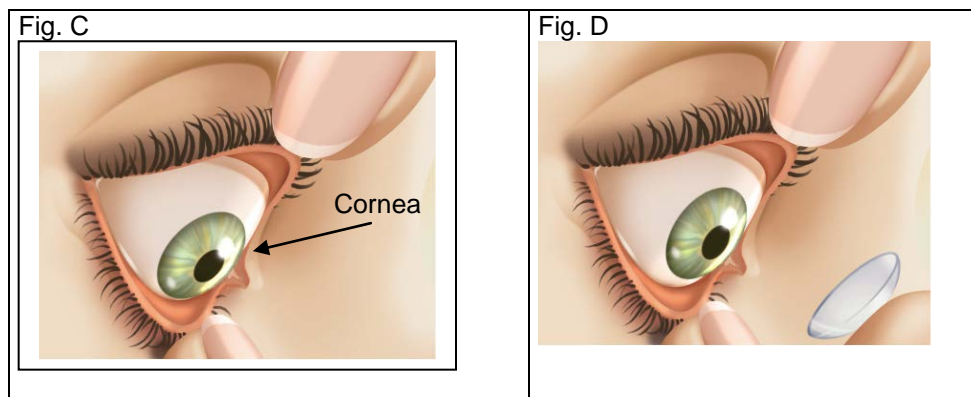
## 7.4. Placing the Lens on the Eye

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.

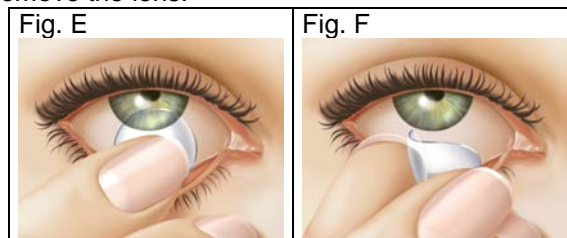
- a. Wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- b. Remove the right lens first. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that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

### **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 a 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 can not 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 eyecare practitioner. 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 MONOVISION WEARER

**Monovision:** a treatment technique often prescribed for people age 40 and over who have presbyopia. Presbyopia occurs as part of the natural aging process. The eye's crystalline lens loses its ability to bring close objects into clear focus. Monovision means wearing a contact lens for near vision on one eye and, if needed, a lens for distance vision on the other eye.

The decision to be fit with a monovision correction is made by careful consideration and discussion of your needs with your eye care practitioner.

- You should be aware that there are advantages and tradeoffs to monovision contact lens correction. The benefit of clear near vision in straight ahead and upward gaze available with monovision, may be accompanied by a reduction in your visual acuity and depth perception for distance and near tasks. Some patients experience difficulty adapting to monovision. 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 monovision lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of 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 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 glasses to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.



## 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	Accidently 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.

**It is essential that you follow your eyecare practitioner's directions regarding this important step of building up your wear time.**

### Prescribed Wearing Schedule for Adaptation to contact lenses

Day	Wearing Time (Hours) Recommended by Eyecare 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.

Dr: \_\_\_\_\_

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

**NAME AND ADDRESS OF MANUFACTURER:**

CooperVision, Inc.  
711 North Road  
Scottsville, NY 14546  
Toll Free Number: 1(800) 341-2020  
[www.coopervision.com](http://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.*

**BIOFINITY® (comfilcon A)  
Soft (Hydrophilic) Contact Lenses  
For Planned Replacement**

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

**SYMBOLS KEY**

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner
	See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.**

**DESCRIPTION**

**BIOFINITY** (comfilcon A) Contact Lenses are available as spheric, aspheric, toric and multifocal lens designs.

The lenses are made from a material containing 48% water and 52% comfilcon A, a silicone-containing hydrogel. The lenses have a tint (phthalocyanine blue) which is added to make the lens more visible for handling.

**BIOFINITY** and **BIOFINITY XR SPHERE** (comfilcon A) contact lenses parameters:

- o Diameter: 13.5 mm to 15.0 mm
- o Base Curve: 8.0 mm to 9.5 mm
- o Center Thickness: 0.065 mm to 0.60 mm (varies with power)
- o Powers: -20.00 D to +20.0 D

**BIOFINITY ENERGYS™ ASPHERE** (comfilcon A) contact lenses parameters:

- o Diameter: 13.5 mm to 15.0 mm
- o Base Curve: 8.0 mm to 9.5 mm
- o Center Thickness: 0.065 mm to 0.60 mm (varies with power)
- o Powers: -20.00 D to +20.0 D

**BIOFINITY TORIC** (comfilcon A) and **BIOFINITY XR TORIC** (comfilcon A) contact lenses parameters:

- o Diameter: 13.5 mm to 15.0 mm
- o Base Curve: 8.0 mm to 9.5 mm
- o Center Thickness: 0.08 mm to 0.60 mm (varies with power)
- o Powers: -20.00 D to +20.0 D
- o Cylinder: -0.25 D to -5.75 D
- o Axis: 0° to 180°

**BIOFINITY MULTIFOCAL** (comfilcon A) and **BIOFINITY XR MULTIFOCAL** (comfilcon A) contact lenses parameters:

- o Diameter: 13.5 mm to 15.0 mm

- o Base Curve: 8.0 mm to 9.5 mm
- o Center Thickness: 0.08 mm to 0.60 mm (varies with power)
- o Powers: -20.00 D to +20.0 D
- o Addition Powers: +0.50 D to +4.00 D

The physical/optical properties of the lens are:

- o Refractive Index: 1.40
- o Light Transmittance: >97%
- o Surface Character: Hydrophilic
- o Water Content: 48%
- o Specific Gravity: 1.04
- o Oxygen Permeability: 128 x 10<sup>-11</sup> (cm<sup>2</sup>/sec)(ml O<sub>2</sub>/ml x mmHg) 35°C (Coulometric method)

**Call our Customer Service Department at (800) 341-2020 for current availability.**

**ACTIONS**

When placed on the cornea in its hydrated state, the **BIOFINITY** (comfilcon A) Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

**INDICATIONS FOR USE**

**Spherical and Aspherical**

**BIOFINITY** and **BIOFINITY XR SPHERE** (comfilcon A) 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.

**BIOFINITY ENERGYS™ ASPHERE** (comfilcon A) 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**

**BIOFINITY TORIC** (comfilcon A) and **BIOFINITY XR TORIC** (comfilcon A) 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 -5.75 diopters.

**Multifocal**

**BIOFINITY MULTIFOCAL** (comfilcon A) and **BIOFINITY XR MULTIFOCAL** (comfilcon A) 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 +0.50 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.

The **BIOFINITY** (comfilcon A) Soft (Hydrophilic) Contact Lenses have been approved for extended wear for up to 6 nights /7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Practitioner.

Eye Care Practitioners may prescribe the lens for frequent replacement wear, with cleaning, disinfecting and scheduled replacements (see WEARING SCHEDULE)

**CONTRAINDICATIONS (REASONS NOT TO USE)**

Do not use the **BIOFINITY** lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution, which is to be used to care for any **BIOFINITY** lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

**WARNINGS:**

**PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.**

It is essential that the patient follows the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case.

Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:

i. **Soaking and Storing the Lenses**

**Instruction for Use:**

Use only fresh multi-purpose (contact lens disinfecting) solution each time the patient soaks (stores) the lenses.

**WARNING:**

Do not reuse or “top off” old solution left in the lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness.

“Topping-Off” is the addition of fresh solution to solution that has been sitting in the case.

ii. **Rub and Rinse Time**

**Instruction for Use:**

- Rub and rinse the lenses according to the recommended lens rubbing and rinsing times in the labeling of the multi-purpose solution to adequately disinfect the lenses.

**WARNING:**

- Rub and rinse the lenses for the recommended amount of time to help prevent serious eye infections.
- Never use water, saline solution, or rewetting drops to disinfect the lenses. These solutions will not disinfect the lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

iii. **Lens Case Care**

**Instruction for Use:**

- Empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to dry.
- Replace the lens case according to the directions given by the eye care professional or the labeling that came with the case.
- Contact lens cases can be a source of bacterial growth.

**WARNING:**

Do not store the lenses or rinse the lens case with water or any non-sterile solution. Only use fresh multi-purpose solution to not contaminate the lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

iv. **Water Activity**

**Instruction for Use:**

- Do not expose the contact lenses to water while wearing them.

**WARNING:**

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If the lenses have been submerged in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask the eye care practitioner (professional) for recommendations about wearing the lenses during any activity involving water.

v. **Discard Date on Multi-purpose Solution Bottle**

**Instruction for Use:**

- Discard any remaining solution after the recommended time period indicated on the bottle of multi-purpose solution used for disinfecting and soaking the contact lenses.
- The Discard date refers to the time to safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

**WARNING:**

Using the multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

- To avoid contamination, DO NOT touch tip of container to any surface. Replace cap after using.
- To avoid contaminating the solution, DO NOT transfer to other bottles or containers.

**EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF THE FOLLOWING IS EXPERIENCED:**

- **Eye Discomfort,**
- **Excessive Tearing,**
- **Vision Changes;**
- **Loss of Vision,**
- **Eye Redness**
- **Or Other Eye Problems**

**PATIENTS SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THE EYE CARE PRACTITIONER.**

- 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 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.

- Patients should be cautioned that proper use and care of the contact lenses and lens care products, including lens cases, are essential for the safe use of these products. It is essential that patients follow their Eye Care Practitioner's directions and all labeling instructions for proper use of lenses and lens care products. Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. Additionally, they should clean and rinse their lens case between uses as recommended by their Eye Care Practitioner. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- The result of a study<sup>1</sup> indicate the following:
  - a. The overall annual incidence of 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 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 ulcerative keratitis may be reduced by carefully following directions for lens care, including cleaning the lens case.
  - e. The risk of ulcerative keratitis among contact lens users who smoke is estimated to be 3 to 8 times greater than among non-smokers.
  - f. If patients experience eye discomfort, excessive tearing, vision changes, redness of the eye or other problems, they should be instructed to immediately remove their lenses and promptly contact their Eye Care Practitioner. It is recommended that contact lens wearers see their Eye Care Practitioner routinely as directed.

<sup>1</sup>NewEnglandJournalofMedicine,September21,1989;321(12),pp.773-783

**PRECAUTIONS**

**Special Precautions for Eye Care Practitioners**

- Due to the small numbers of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the Eye Care Practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing Eye Care Practitioner.
- Patients who wear contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with any **BIOFINITY** contact lenses until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become discolored. Whenever fluorescein is used in the eyes, the eyes



should be flushed with a sterile saline solution that is recommended for in-eye use.

- Before leaving the Eye Care Practitioner's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her. Eye Care Practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

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

- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Never use solutions recommended for conventional hard contact lenses only.
- Always follow the directions in the package inserts for the use of contact lens solutions.
- Always use a chemical lens care system. Use of heat care system can damage the comfilcon A contact lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her Eye Care Practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
- Always handle lenses gently and avoid dropping them.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, and wearing instructions in the Patient Instructions for **BIOFINITY** contact lenses and those prescribed by the Eye Care practitioner.
- Never wear lenses beyond the period recommended by the Eye Care Practitioner.
- Always discard disposable lenses and lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the Eye Care Practitioner.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Ask the Eye Care Practitioner about wearing the lenses during sporting activities.
- Inform the doctor (Health Care Practitioner) about being a contact lens wearer.
- Always contact the Eye Care Practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

#### ADVERSE REACTIONS

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

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less than when the lens was first placed on the eye.
- Feeling that something is in the eye such as a foreign body or a scratched area.
- Excessive watering (tearing) of the eyes.
- Unusual eye secretions.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).

- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

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

- **Immediately remove the lenses.**
- If the discomfort or the problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect both lenses; then reinsert them. After reinsertion, if the problem continues the patient should **immediately remove the lenses and consult the Eye Care Practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

#### FITTING

Conventional methods of fitting contact lenses apply to all **BIOFINITY** contact lenses. For a detailed description of the fitting techniques, refer to the **BIOFINITY** Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.  
711 North Road  
Scottsville, New York 14546  
1-800-341-2020  
www.coopervision.com

#### WEARING SCHEDULE

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

CooperVision recommends that all **BIOFINITY** lenses be discarded and replaced with a new lens on a frequent replacement basis. The eye care practitioner is encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.

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

DAY	Hours	Day	Hours
1	6	4	12
2	8	5	14
3	10	6	All waking hours

The Eye Care Practitioner should determine the wearing and replacement schedule, based upon the patient's history and their ocular examination, as well as the practitioner's experience and clinical judgment.

**EXTENDED WEAR:** **BIOFINITY** contact lenses may be prescribed for daily wear and extended wear for up to 6 nights/ 7 days of continuous day and night wear. Not all patients can achieve the maximum wear time. It is recommended that the contact lens wearer be evaluated on a daily wear schedule. If successful, then a gradual introduction of extended wear can be followed as determined by the prescribing Eye Care Practitioner.

Once removed, it is recommended that the lens remain out of the eye for a period of rest overnight or longer and discarded in accordance with the prescribed wearing schedule. The Eye Care Practitioner

should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion and removal.

### LENS CARE DIRECTIONS

Eye Care Practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting. Do not put lenses in the mouth.
- The patient should always have a spare pair of lenses at all times.

### General Lens Care: (For Planned Replacement)

Basic Instructions:

- Always use **fresh, unexpired** lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care systems **unless indicated on solution labeling**.
- 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, (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme cleaner is not recommended.
- The eye care practitioner should recommend a care system that is appropriate for **BIOFINITY** contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow directions.
- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfection solution to remove 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 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 following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on the storage of lenses.
- 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 lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your Eye Care Practitioner.
- Eye Care Practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

### CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide):

- **Clean** the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning** and rinsing, to **disinfect**, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the Eye Care Practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized before** wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- 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

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recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline. Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.

- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- **CAUTION:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement in the eye should reduce the potential for irritation.

### LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and rinsed with solution recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the Eye Care Practitioner.

### CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any **BIOFINITY** lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

### CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues more than 5 minutes, the patient should immediately consult the Eye Care Practitioner.

### EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: **FLUSH THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

### HOW SUPPLIED

Each lens is supplied sterile in a blister pack containing buffered isotonic saline solution. The blister is labeled with the base curve, diameter, dioptric power, manufacturing lot number, and expiration date of the lens.

**DO NOT USE IF THE BLISTER PACK IS BROKEN OR THE SEAL HAS BEEN DAMAGED**

### REPORTING OF ADVERSE REACTIONS

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



CooperVision  
Attn: Product Services  
711 North Road  
Scottsville, New York 14546  
(800) 341-2020  
www.coopervision.com

Hamble, Southampton, SO31 4RF, UK

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