**INDICATIONS (USES):**

Medium to focus light rays on the retina.

**ACTIONS:**

When placed on the cornea in its hydrated state, any lens

**PRECAUTIONS:**

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

Do not use any 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 eyes.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoplasia (reduced corneal sensitivity), if not aphakic.
- Any systemic disease that may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exacerbated 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 for care of 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:**

Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner’s directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal staining, may develop rapidly and lead to loss of vision.
- All contact lens wearers must see their eye care practitioner as directed.
- Daily wear lenses 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.
- The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses.
- Studies have been shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If the patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lenses and promptly contact his or her eye care practitioner.

**ADVERSE EFFECTS:**

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

- Eyes stinging, burning, or itching (irritation), or other eye pain.
- Comfort is less 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 sensations.
- Redness of the eyes.
- Reduced sharpness of vision (poor visual acuity).
- Blurred vision, rainbows, or halos around objects.
- Sensitivity to light (photophobia).
- Dry eyes.

**BIOfinity contact lenses and those prescribed by the eye care practitioner.

- Not wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Inform the employer of being a contact lens wearer.
- Avoid all contact lenses and those prescribed by the eye care practitioner.
- 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.
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 patient notices 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 lenses 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:

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 check-ups, 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:

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LENS CARE DIRECTIONS:

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

LENS CARE DIRECTIONS:

(To First Clean and Rinse, the Disinfected Lenses)

**General Lens Care**

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use fresh, unexpired lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting. Do not put lenses in the mouth.
- 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-based solution 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 DISINFECT (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, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.** Leave the lenses in the unopened storage case until ready to put on the eyes.
- **CAUTION:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement in the eye should reduce the potential for irritation.

LENSES THAT ARE CHEMICALLY DISINFECTED MAY ABSORB INGREDIENTS FROM THE DISINFECTING SOLUTION WHICH MAY BE IRRITATING TO THE EYES. A THOROUGH RINSE IN FRESH STEERL SALINE SOLUTION PRIOR TO PLACEMENT IN THE EYE SHOULD REDUCE THE POTENTIAL FOR IRRITATION.

Lenses 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 and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline solution before handling.

To rehydrate the lens:
- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storage solution for at least one hour until it returns to a soft state.
- Clean the lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, if the surface remains dry, the lens should not be used unless it has been examined by the eye care practitioner.

**CARE FOR A STICKING (NONMOVING) LENS:**

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

**EMERGENCIES:**

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) splash 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, dioptic 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:

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

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