



CooperVision

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

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

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

SOFT (HYDROPHILIC) CONTACT LENSES

PRACTITIONER FITTING GUIDE

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LENS FORM AND CHARACTERISTICS

The BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric (comfilcon A), BIOFINITY XR Toric (comfilcon A), BIOFINITY Multifocal (comfilcon A), and BIOFINITY XR Multifocal (comfilcon A) Soft (Hydrophilic) Contact Lens is a hemispherical flexible shell that covers the cornea and extends slightly beyond the limbus, covering a portion of the adjacent sclera. In the hydrated state, the lens tends to conform to the curvatures of the anterior eye.

The lens material (comfilcon A), when hydrated, consists of 52% comfilcon A and 48% water by weight when immersed in buffered saline. The material has a refractive index of 1.40 and the lens has a visible light transmittance of > 97%. The oxygen permeability of the material at 35°C is 128×10^{-11} (cm²/sec) (ml O₂/ml x mm Hg) determined by the coulometric method.

The hydrophilic properties of the BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric (comfilcon A), BIOFINITY XR Toric (comfilcon A), BIOFINITY Multifocal (comfilcon A), and BIOFINITY XR Multifocal (comfilcon A) Soft (Hydrophilic) Contact Lens require that it be maintained in a fully hydrated state in a solution having a tonicity compatible with tears. The lens material is stable, has good mechanical strength, and is elastic in its hydrated state. If the lens dries out, it will become hard and appear somewhat warped. If the lens dries out advise patients to discard the dried out lens.

LENS PARAMETERS AVAILABLE

BIOFINITY (comfilcon A)

Diameter	14 mm
Base Curve	8.6 mm
Center Thickness	0.065 mm to 0.60 mm (varies with power)
Sphere Power	-20.00 D to +20.00 D; +0.25 D steps

Also for Toric:

Cylinder Power	-0.25 D to -5.75 D
Axis	0° to 180° in 10° increments

Also for Multifocal:

Add Power	+0.50 D to +4.00 D
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See Price List for Detailed Availability

FITTING CONCEPT

The fitting concept is based on the draping effect of a high water content lens. Various base curves are achieved when the peripheral portion of the BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric (comfilcon A), BIOFINITY XR Toric (comfilcon A), BIOFINITY Multifocal (comfilcon A), and BIOFINITY XR Multifocal (comfilcon A) (hydrophilic) contact lens flexes to the curvature of the cornea. The water content of the lens combined with thin lens sections permits excellent draping across a broad range of corneal curvatures.

The draping effect of the lens automatically adjusts to the sagittal height for each cornea. The lens parallels the apex of the cornea providing broad apical contact of the central cornea, vaulting or “clearance” of the limbus and light scleral bearing.

PATIENT SELECTION

An examination, including history, refraction, keratometry, biomicroscopy, and other pertinent tests and measurements should be performed. If the patient has the necessary qualifications and no contraindications exist, the patient may be considered for fitting.

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 (USES)

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.

BIOFINITY TORIC 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 -5.75 diopters.

BIOFINITY MULTIFOCAL and BIOFINITY XR MULTIFOCAL (comfilcon A) 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 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) Contact Lenses may be prescribed for extended wear for up to 6 nights and 7 days of continuous wear. It is recommended that the contact lens wearer be first evaluated on a Daily Wear schedule prior to overnight wear. The lenses may be prescribed for either one week disposable wear or for frequent replacement with cleaning, disinfection and scheduled replacement. When prescribed for frequent replacement, the lenses must be cleaned and disinfected using a chemical disinfection system only.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS

Please refer to the Package Insert in the back of this guide.

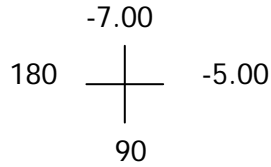
FITTING PROCEDURE

- Perform a preliminary evaluation to determine distance refraction as well as to rule out contraindications to contact lens wear as described in the Package Insert.
 - Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane.
 - Place the lens on the eye. Allow the lens to remain on the eye long enough to achieve a state of equilibrium. Small variation in the tonicity, pH of the lens solutions and individual tear composition may cause slight changes in fitting characteristics.
 - The lens should cover the patient's cornea fully, provide discernible movement (0.10mm to 1.00mm) after blink, be comfortable for the patient and provide satisfactory visual performance.
 - Full coverage of the cornea is defined as the lens edge extending beyond the limbus area in all directions. Initial lens evaluation must be done after at least 10 minutes of lens wear to allow the lens to stabilize and any tearing to subside.
 - Following a blink, the lens should move vertically on the patient's eye about 0.10mm to 1.00mm.
 - When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.
1. Determine Patient's Power Requirements:
 - a. Convert the patient's spectacle Rx to minus cylinder form.
 - b. The sphere and cylinder power of the contact lens prescription is the same as the spectacle Rx when the power is less than 4.00 D in both meridians. When the power is greater than or equal to 4.00 D, vertex the prescription to the spectacle plane.

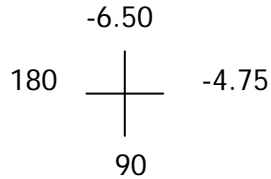
(See **EXAMPLE**) to determine the most appropriate axis.

EXAMPLE: History of nasal rotation on eye being fit

OD Spectacle Rx: -5.00 -2.00 x 180



OD Contact Lens Rx: -4.75 -1.75 x 180



Clinical experience has shown that the initial spherical and cylindrical power may vary by +/- 0.25 diopters and the axis of the initial lens may vary by 5 degrees on cylinders up to 2.00 diopters and 3 degrees for cylinders over 2.00 diopters without diminishing visual acuity of the patient.

If you wish, call our Customer Service Department with the patient's spectacle Rx and central K readings and they will make the proper compensations for your BIOFINITY Rx.

2. If the flatter keratometry value is 46.50D or less, choose the 8.5 base curve.
3. **Equilibration:**
Allow a minimum of 15 minutes for the trial lenses to equilibrate after insertion, before evaluation of fit and vision.
4. **Check Lens Fit:**
A properly centered lens will provide complete corneal coverage at all times. Decentration which leaves 0.50mm or less of the lens extending onto the sclera in any position will likely result in decreased or fluctuating vision.

The diameter of the lens should be such that the lens extends past the limbus 1.0 - 2.0mm on both the nasal and temporal sides of the cornea.

Movement of the lens with blinking is important to maintain optimum corneal physiology. The lens should move 0.50 - 1.5mm when the patient blinks and lag 0.50 - 1.5mm in upward gaze. While some patients may be able to maintain adequate corneal health with less movement, tight lenses should be avoided. If the lens is exhibiting minimal movement, apply a slight amount of digital pressure against the lower lid. The lens should move freely and easily, and return to the centered position when released. A tight lens will resist movement.

5. **To Determine the Optimum Power and Axis for the Final Lens:**
 - a. Measure the amount of lens rotation, if any. Be sure the eye for which lens rotation is being evaluated is sighting straight ahead (i.e., down the optic axis of the slit lamp), as parallax resulting from misalignment can yield inaccurate measurements.
 - b. If acuity is less than desired, do a complete over-refraction to include sphere, cylinder and axis and call CooperVision Consultation Department with the following information:
 - i. Contact lens parameters
 - ii. Over-refraction (sphere, cylinder and axis) and visual acuity
 - iii. Lens specifications (base curve, sphere, cylinder, axis)
 - iv. Any lens rotation
6. When lenses are dispensed for vision correction, the wearer must be supplied with an appropriate wearing regimen and must fully understand all lens handling and emergency lens care instructions to prevent lens damage as described in the Package Insert and the Patient Information Booklet.

FITTING SUMMARY

Fitting performance and visual response should be confirmed with the prescription lenses prior to dispensing and the management of certain adaptive symptoms should be discussed with the patient prior to dispensing.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight eye redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these mild symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their eye care practitioner.

During the first few weeks of lens wear, patients may report a small amount of secretions on their eyelids, hazy vision on awakening and occasional dryness of the eyes during the day. These symptoms are minor and may be alleviated by using a lubricating/re-wetting solution.

PATIENT MANAGEMENT AND FOLLOW-UP CARE

1. DISPENSING VISIT

The lenses are delivered sterile, immersed in buffered saline solution, and supplied in a blister pack. Insertion and removal is done in the conventional manner used for soft hydrophilic contact lenses.

Evaluate patient's lenses on the eyes for physical fit as described in the preceding discussion. Instruct the patient on the technique for soft lens insertion and removal, as well as all aspects of lens care, including cleaning, disinfection, storage, and handling. Dispense to the patient written instructions on lens care and a copy of the BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric and BIOFINITY XR Toric (comfilcon A) and BIOFINITY Multifocal and BIOFINITY XR Multifocal (comfilcon A) soft (hydrophilic) Contact Lens Patient Instruction Booklet. Review these instructions carefully with your patient.

2. RECOMMENDED WEARING SCHEDULE

It is recommended that a contact lens-wearing patient see his or her Eye Care Practitioner twice each year or, is so directed, more frequently. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

Daily wear: Patients tend to over wear the lenses initially. Therefore, practitioners should stress to these patients the importance of adhering to a proper initial daily wearing schedule. The practitioner should determine the appropriate wearing schedule and replacement schedule, which he or she should provide to the patient.

Extended wear: BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric and BIOFINITY XR Toric (comfilcon A) and BIOFINITY Multifocal and BIOFINITY XR Multifocal (comfilcon A) are approved for up to 6 nights and 7 days of continuous wear.

3. FOLLOW-UP CARE

Follow-up care includes routine periodic progress examinations, management of specific problems, if any, and review of proper lens care and handling. Barring complications, the recommended schedule of follow-up examinations should be:

Daily Wear

- a. One week post-dispensing.
- b. One month after dispensing.
- c. Three months after dispensing.
- d. Every six months thereafter.

4. PROCEDURES AND INSTRUMENTATION FOR FOLLOW-UP VISITS (WITH LENSES ON, PREFERABLY FOR AT LEAST SIX HOURS)

- a. Record patient's symptoms, if any.
- b. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
- b. Check visual acuity and refract over lens.
- c. Check for residual astigmatism with the aid of a refractor or loose trial lenses (do not use autorefractor).
- d. Biomicroscopy:
 - i. Examine the conjunctiva and lids.
 - ii. Check for lens edge impingement of the sclera, indentation, or vessel blanching, using low to medium magnification.
 - iii. Check integrity of lens edges.
 - iv. Check for surface deposits, deep scratches or edge nicks.

5. Procedures for Follow-Up Visits (with lenses removed):

- a. Perform a biomicroscopic examination of the cornea and limbus, both with and without the use of fluorescein; check for edema, injection, vascularization, corneal staining, or any indication of iritis.
- b. Measure corneal curvatures with keratometer and compare to original values and mire quality. Any deviations from baseline (pre-fit) should be noted.
- c. Check for spectacle blur shortly after lenses are removed. Record all measurable values and any remarkable findings.

If any of the above observations are judged to be abnormal, professional judgment is to be used in alleviating the problem and restoring the eye to optimal conditions. If the criteria for a well-fitted lens are not reached during any follow-up examinations, the patient's fitting procedure should be repeated. The patient should be refitted, with necessary follow-up examinations also repeated.

CLINICAL ASSESSMENT

1. CRITERIA OF A WELL-FITTED LENS

A well-fit BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric and BIOFINITY XR Toric (comfilcon A), and BIOFINITY Multifocal and BIOFINITY XR Multifocal (comfilcon A) Soft (Hydrophilic) Contact Lens best satisfies the following criteria:

- Full corneal coverage.
- Good centration (concentric about the visible iris).
- Satisfactory lens sag (in up gaze 0.10 to 1.00mm is ideal) with the blink.
- The lens moves freely when manipulated with digital pressure against the lower lid.
- Satisfactory comfort response by the patient.
- Satisfactory vision response by the patient.

2. CHARACTERISTICS OF A TIGHT (STEEP) LENS

A tight BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric and BIOFINITY XR Toric (comfilcon A), and BIOFINITY Multifocal and BIOFINITY XR Multifocal (comfilcon A) Soft (hydrophilic) Contact Lens would display some or all of the following characteristics:

- Good centration.
- Little or no up gaze sag.
- The lens resists movement when manipulated with digital pressure against the lower lid.
- Good comfort
- Vision may be blurred and clear immediately following blink.
- Bubble(s) under the lens.
- Conjunctival indentation and/or blanching of limbal vessels at the lens edge.
- Limbal-conjunctival hyperemia.

3. CHARACTERISTICS OF A LOOSE (FLAT) LENS

A loose BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric and BIOFINITY XR Toric (comfilcon A), and BIOFINITY Multifocal and BIOFINITY XR Multifocal (comfilcon A) Soft (hydrophilic) Contact Lens will display some or all of the following characteristics:

- Decentration (usually temporally and/or superiorly).
- Excessive up gaze sag.
- Reduced comfort response-usually lower lid sensation.
- Lens edge standoff.
- Unstable vision.

MONOVISION FITTING GUIDELINES

1. Patient Selection

A. Monovision Needs Assessment

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than 0.75 diopter) in one eye may not be a good candidate for monovision.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

- (1) visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
- (2) driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method

For anisometric corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example:

A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left with a lens.

A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines and base curve selection described earlier in the guide.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptation symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions:

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
 - Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
 - Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.
- * The decision to fit a patient with a monovision correction is most appropriately left to the Eye Care Practitioner in conjunction with the patient after carefully considering the patient's needs.
- * All patients should be supplied with a copy of the Patient Instruction manual.

CARE OF LENSES

Please refer to the "Lens Care Directions" section of the Package Insert.

PATIENT CARE OF LENSES

Please refer to the Package Insert and the Patient Information Booklets for information pertaining to Cleaning/Disinfecting, Lens Care, and Handling Instructions.

HOW SUPPLIED

Each lens is supplied sterile in a blister containing sterile isotonic buffered saline solution. The blisters are packed in boxes. The following information is provided: the base curve, diameter, dioptric power, manufacturing lot number of the lens and the expiration date of the product.

REPORTING ADVERSE ACTIONS

All serious adverse experiences and adverse reactions in patients wearing the BIOFINITY and BIOFINITY XR Sphere (comfilcon A), and BIOFINITY ENERGYS™ Asphere (comfilcon A), BIOFINITY Toric and BIOFINITY XR Toric (comfilcon A), and BIOFINITY Multifocal and BIOFINITY XR Multifocal (comfilcon A) Soft (Hydrophilic) Contact Lens or experienced with the lenses should be reported to:

CooperVision, Inc.
711 North Road
Scottsville, NY 94080
USA
800-341-2020

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






- 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

PACKAGE INSERT

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:

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: 128×10^{-11} (cm²/sec)(ml O₂/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 submersed 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 study¹ 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 wears see their Eye Care Practitioner routinely as directed.

¹NewEnglandJournalofMedicine,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 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