Biocomfort Toric (ocufilcon D) Soft Contact Lens
Package Inserts

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 eyecare practitioner should provide the patient with the appropriate patient instructions and/or patient information booklet which pertains to the patient's prescribed lenses.

SYMBOLS KEY:

The following symbols may appear on the label or carton.

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

FOR VISION CORRECTION USE

INDICATIONS (USES):

Biocomfort Toric contact lenses with the ultraviolet blocker are indicated for the correction of visual acuity in persons with non-aphakic, non-diseased eyes which manifest myopia, hyperopia, or astigmatism in powers from –10.00 to +10.00 diopters and astigmatic corrections from –0.25 to –10.00 diopters.

The eye-care practitioner may prescribe **Biocomfort Toric** lenses for single-use disposable wear or for scheduled replacement wear, with cleaning, disinfection, and scheduled replacement (see "Wearing Schedules"). When prescribed for scheduled replacement wear, **Biocomfort Toric** lenses may be disinfected only with a chemical (not heat) disinfection system.

DESCRIPTION:

All UV-blocking **Biocomfort Toric** contact lenses are available as hemispherical flexible shells of the following dimensions:

- Diameter: 14.5 mm
- Center Thickness: 0.0745 mm to 0.178 mm (depending upon power)
- Inside Spherical Radius: 8.66 mm to 9.89 mm
- Spherical Powers: +10.00 D to -10.00 D
- Cylinder Powers: -0.25 D to -10.00 D
- Axis: 0° to 180° in 10° increments

The lens material is a hydrophilic polymer of 2-hydroxyethyl methacrylate and methacrylic acid cross-linked with ethylene glycol dimethacrylate (45.0%) and water (55.0%).

The physical parameters of the lens are as follows:

- Refractive Index: 1.405
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability: 19.6 x 10^{-11} (cm^2/sec)(ml O_2/ml x mmHg) 35°C (Coulometric method)
- Light Transmittance: 97.0%
- Wearing Schedule: Daily Wear
- Replacement Schedule: Monthly Disposable

Biocomfort Toric contact lenses, tinted for visibility purposes, are tinted from edge to edge using one of the following color additives: 7, 16 dichloro-6, 15-dihydro-5, 9, 14, 18-anthrazinetetrone (Vat Blue 6 Dye), which is added in-monomer prior to polymerization.

Biocomfort Toric visibility-tinted contact lenses are available with a proprietary benzophenone UV absorbing monomer. UV-blocking **Biocomfort Toric** contact lenses help protect against transmission of harmful ultraviolet radiation to the cornea and into the eye. The transmittance of ultraviolet radiation is measured at two representative lens powers, -2.50 diopters (center thickness of 0.07 mm) and -8.00 diopters (center thickness of 0.06 mm), through the central 3- to 5-mm portions of the lenses.1, 2 (Please refer to accompanying transmittance curve graph).

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

Biocomfort Toric contact lenses may be prescribed for daily wear in the **Biocomfort Toric** Scheduled Replacement Program.

In the Scheduled Replacement Program, patients should wear **Biocomfort Toric** lenses as prescribed by their eye-care practitioners. Each time the patient must remove his or her lenses before the prescribed replacement time period has elapsed, the patient must clean and disinfect the lenses before replacing them on the eyes. The eye-care practitioner is encouraged to determine a lens replacement schedule based upon the response of the patient.

ACTIONS:

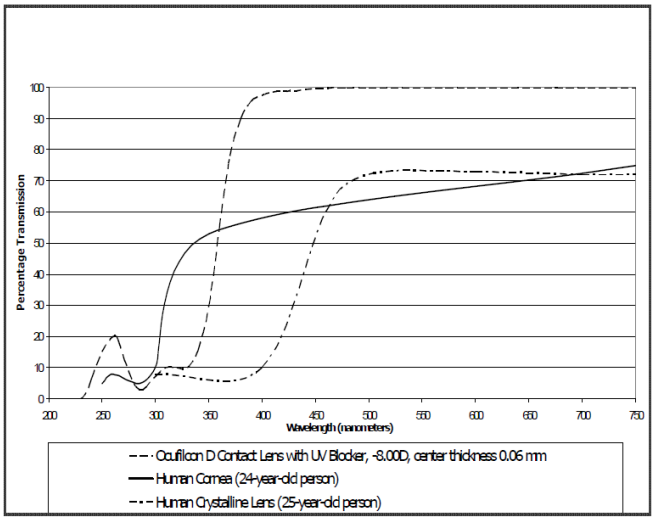
In its hydrated state, the **Biocomfort Toric** contact lens, when placed on the human cornea, acts as a corrective refracting medium to focus light rays on the retina.

The visibility-tinted **Biocomfort Toric** contact lens allows the lens to become readily visible to the wearer when it is not on the eye.

Transmittance of ultraviolet light through the contact lens for two representative lens powers is as follows:

	UVA (380 nm~315 nm)	UVB (315 nm~280 nm)
-2.50 diopters:	37.7%	3.9%
-8.00 diopters:	39.8%	6.8%

NOTE: ***Long-term exposure to ultraviolet radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors, such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been performed which demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Patients should consult their eye-care practitioners for more information.***



1. Lerman, S., *Radiant Energy and the Eye* (New York: MacMillan, 1980), p. 58, Figure 2-21.
2. Transmittance profile of the human cornea of a 24-year-old person. Waxler, M., and V. M. Hitchens, *Optical Radiation and Visual Health* (Boca Raton: CRC Press, 1986), p. 19, Figure 5. Transmittance profile for the human crystalline lens of a 25-year-old person.

CONTRAINDICATIONS (REASONS NOT TO USE):

Patients **SHOULD NOT USE Biocomfort Toric** contact lenses when any of the following conditions exist:

- Acute and subacute inflammation or infection in the anterior chamber of the eye.
- Any active eye disease, injury, or abnormality affecting the cornea, conjunctiva, or eyelids.
- Insufficiency of lachrymal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or which may be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or by using contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which must be used to care for the lens.
- Use of a medication that is contraindicated, including eye medications.
- Patient history
  (i.) of recurring eye or eyelid infections, including sties;
  (ii.) of adverse effects associated with contact lens wear; or
  (iii.) of intolerance or abnormal ocular response to contact lens wear.
- History of patient non-compliance with contact lens care and disinfection regimens, wearing restrictions, wearing schedule, or follow-up visit schedule.
- Patient inability or unwillingness, because of age, infirmity, or other mental or physical conditions, or because of an adverse working or living environment, to understand or comply with any warnings, precautions, restrictions, or directions. Additionally, patients who require only vision correction and
  (i.) who would not, or could not, adhere to a recommended care system for lenses; or
  (ii.) who are unable to place and remove lenses should not be provided with them.

WARNINGS:

Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and with using contact lens-care products. Therefore, after a thorough eye examination, including appropriate medical background, the prescribing practitioner must fully apprise patients of all the risks associated with contact lens wear. To minimize these risks, the practitioner must emphasize to the patient the need for strict compliance with the care regimen (including cleaning of the lens case); wearing restrictions; wearing schedules; and followup visit schedule.

Since eye injury can develop rapidly, it is most important that eye-care practitioners instruct their patients as to the possible signs or symptoms of problems associated with contact lens wear. Further, eye-care practitioners should advise their patients to remove their lenses immediately and be examined by the prescribing practitioner or by a corneal specialist in the event they experience any such signs or symptoms (including those listed below under “Adverse Effects”).

Research has shown that the risk of ulcerative keratitis is greater among users of extended-wear contact lenses than it is among users of daily-wear contact lenses. The risk among extended-wear lens-wearing patients increases with the number of consecutive days that the patient wears the lenses between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea’s resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when the patient has not adhered to a regular and periodic lens removal and disinfection or disposal schedule; improper lens disinfection or cleaning by the patient; contamination of lens-care products; accumulation of lens deposits; damage to the lenses; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. Additionally, smoking increases the risk of ulcerative keratitis in contact lens-wearing patients.

While the great majority of patients successfully wear contact lenses, extended wear of lenses is also reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates and
endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of lens wear.

The reversibility of endothelial effects associated with contact lens wear has not yet been established. Consequently, eye-care practitioners’ views of extended wearing schedules vary; some practitioners do not prescribe extended wearing schedules at all, while others prescribe flexible wearing schedules, which vary from occasional contact lens wear to, in certain patients, extended wearing periods ranging from one to seven days/six nights with specified intervals of no lens wear. Ultimately, the prescribing eye-care practitioner should determine the appropriate wearing time of soft contact lenses used for extended wear, as well as the appropriate replacement schedule. Additionally, the practitioner should determine the patient’s lens-care regimen (if appropriate) and schedule for follow-up visits.

PRECAUTIONS:

In prescribing contact lenses, eye-care practitioners should observe these precautions carefully. It is also strongly recommended that practitioners review with their patients the appropriate Patient

Information Booklet (either for the Disposable Wear Program or for the Scheduled Replacement Program).

- In the event a patient must remove a lens from the eye because dust, a foreign body, or some other contaminant gets on the lens, or because the lens becomes dehydrated, the patient should remove that lens and clean and disinfect it before replacing it on the eye. If a lens becomes dehydrated, the patient should follow the lens care instructions for "**Care for a Dehydrated Lens**."
- Contact lens wear may not be suitable for those in certain occupations, or, in other instances, such persons may require protection equipment.
- In order to minimize the likelihood of lens contamination or of physical trauma to the cornea, lens-wearing patients should avoid environmental fumes, smoke, dust, vapors, and windy conditions.
- It's recommended the use of sterile lens-care solutions. If a particular patient is allergic to preservatives, that patient should use sterile non-preserved solutions and should discard such solutions after the time specified in their label directions.
- Eye injury from irritation or infection and damage to contact lenses may result from lens contamination. Patients should take care to prevent cosmetics, lotions, soaps, creams, hair sprays, or deodorants from coming into contact with their lenses.
- Tweezers or other tools should not be used by patients to remove lenses from lens containers; rather, the contents of a lens container should be poured into the hand.
- Practitioners should instruct their patients as to the proper manner to promptly remove their lenses, and patients should be able to demonstrate the ability to do so.
- Fluorescein should not be used while **Biocomfort Toric** lenses are on the patient's eye. The lenses absorb this dye and become discolored. In the event fluorescein does come in contact with the lenses while they are on the patient's eye, the eyes should be flushed thoroughly with a sterile saline solution recommended for in-eye use, and new lenses should be inserted only after at least one hour.
- A lens must move freely on the eye for a proper fit.
- After removal of the lenses from the lens case, to prevent contamination and to help avoid serious eye injury, the patient should always empty and rinse the lens case with fresh rinsing solution and allow it to air-dry between each lens disinfection cycle.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Contact lens-wearing patients should be instructed to inform their physicians that they wear contact lenses; further, patients' physicians should consult their eye-care practitioners before using any medication in the eye.
- Certain medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and medications for motion sickness) may cause dryness of the eye, increased lens awareness, or blurred vision. Should these conditions exist, proper remedial measures should be prescribed. Depending on the severity, such measures could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medications are being used.
- As with any contact lens, follow-up visits are necessary to better ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Practitioners should caution their patients wearing **Biocomfort Toric** lenses on a daily-wear schedule to remove their lenses before sleeping.

ADVERSE EFFECTS:

Patients should be informed that the following problems may occur when they wear contact lenses:

- The eye may be painful or may burn, sting, or itch.
- There may be less comfort than when the lens was first placed on eye.
- There may be a feeling of something in the eye (foreign body, scratched area).
- There may be the potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers, and corneal erosion. There may be the potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, infection, tarsal abnormalities, iritis, and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering (tearing), unusual eye secretions, or redness of the eye.
- Poor visual acuity; rainbows or halos around objects; photophobia; or a feeling of dryness (dry eyes) may also occur if the lenses are worn continuously or for too long a time.

If a patient reports any problems, including, but not limited to, the foregoing, he or she should be instructed to remove his or her lenses immediately. Then:

- If the discomfort or problem stops, the patient should look closely at the lens.
- If the lens has dirt, an eyelash, or other foreign body on it, the patient should be instructed as follows:
- If the patient is in the Scheduled Replacement Program, and if the lens appears undamaged, he or she may clean, disinfect, and reinsert the lens.
- If the lens is or appears in any way damaged, the patient SHOULD NOT put the lens back on the eye. The patient should discard the lens and insert a fresh, new lens on the eye.
- If the patient's problem continues, the patient SHOULD NOT put the lens back on the eye; but rather he or she should immediately contact his or her eye-care practitioner or a physician, who must determine the need for examination, treatment, or referral without delay.
- The patient should be advised that when any of the aforementioned symptoms occur, a serious condition such as infection, corneal ulcer, corneal neovascularization, or iritis may be present and may progress rapidly. The patient should seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage. Less serious reactions, such as abrasions, epithelial staining, and bacterial conjunctivitis, should be treated appropriately to avoid complications.

FITTING

Conventional methods of fitting soft contact lenses apply to these lenses. Prescribing eye-care practitioners must supply their patients with appropriate instructions for wearing, removing, and replacing their lenses, and patients must fully understand all handling and lens-care instructions.

WEARING SCHEDULES:

It is recommended that a contact lens-wearing patient see his or her eye-care practitioner twice each year or, if 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: There may be a tendency for the daily-wear patient to overwear 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.

LENS CARE DIRECTIONS:

Eye-care practitioners should provide their patients with appropriate and adequate instructions and warnings for lens care and handling, and practitioners should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens-wearing schedule and care system selected by the practitioner, the specific instructions for such products, and the particular characteristics of the patient.

For complete information concerning emergency lens care, refer to the Patient Information Booklet for patients in the Disposable Wear Program. Emergency lens care does not apply to lenses worn on a daily-wear basis.

For complete information concerning the care, cleaning, and disinfecting of **Biocomfort Toric** contact lenses, patients should refer to the Patient Information Booklet for the Scheduled Replacement Program.

CARE FOR A DEHYDRATED LENS:

For patients in the Scheduled Replacement Program: If a soft contact lens is off the eye and is exposed to air for a significant period of time, it may become dry and brittle and need to be re-hydrated. If the lens is adhering to a surface such as a counter top, apply sterile saline before handling the lens.

Eye-care practitioners should review the following information on re-hydrating the lens with the patient:

- Handle the lens carefully.
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state.
- Clean and disinfect and re-hydrate lens using a recommended lens-care system.
- If the lens does not become soft after soaking, the lens should not be used until it is examined by the eye-care practitioner.

CARE FOR A STICKING LENS:

If the lens sticks (or stops moving), the patient should be instructed to apply several 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 attempting to remove it. If non-movement of the lens continues after several minutes, the patient should consult with his or her eye-care practitioner immediately.

PRACTITIONER FITTING SETS:

All lenses which have been opened must be discarded after each fitting.

HOW SUPPLIED:

Each **Biocomfort Toric** contact lens is supplied sterile in a container with a normal buffered saline solution. Several containers are packaged in a multi-pack arrangement, each of which is marked with the manufacturing lot number of the lens, the dioptric power, the base curve or series, the diameter, the axis, the cylinder and the expiration date.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing **Biocomfort Toric** contact lenses or experienced with the lenses should be reported to

【Manufacturer】

Cooperision,Inc.
711 North Road, Scottsville, New York 14546, USA

【Manufacturing Site】

1) CooperVision, Inc.
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