

and the presence of ocular debris or environmental contaminants. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.

While the greater majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and endothelial polymegathism, which require consideration of discontinuation of lens wear.

The reversibility of endothelial effects of contact lens wear has not yet been established.

**Abrasions and Infections:** If a lens becomes less comfortable to the wearer than when it was first placed on the wearer's cornea, it may indicate the presence of a foreign body. The lens should be removed immediately and the eye examined. If any eye abrasion, ulceration, irritation, or infection is present, a physician should be consulted immediately.

**Aphakic Patients:** Aphakic patients should not be fitted with the EDGE III (polyacon) soft contact lens during the postoperative period until, in the opinion of the surgeon, the eye has healed completely.

**Lens Care Compliance:** Patients must adhere to the recommended care procedures for the EDGE III (polyacon) soft contact lens. Failure to follow these procedures may result in the development of serious ocular infections.

**Wearing Restrictions:** The EDGE III (polyacon) soft contact lens should be removed before sleeping. The lens should be removed before swimming or in the presence of noxious and irritating vapors. Lens wearers may experience irritation in areas of high environmental pollution.

The EDGE III (polyacon) contact lens should be worn according to the schedule determined by the eye care practitioner.

**Visual Blurring:** When visual blurring occurs, the lens must be removed until the condition subsides.

## PRECAUTIONS

Follow the instructions below to prevent damage to your eye(s) or to your lens(es):

- Before you leave your eye care practitioner's office, you should be able to promptly remove your lens or have someone else be able to remove your lens for you.
- Always follow the recommended lens care system for your EDGE III (polyacon) contact lenses. Use only the recommended lens care solutions and carefully follow recommended directions.
- NEVER USE CONVENTIONAL HARD CONTACT LENS SOLUTIONS, unless indicated for use with soft contact lenses.
- Always use FRESH rinsing and storage solutions.
- Chemical disinfection solutions should not be used with heat, unless indicated on the product label for use with both heat and chemical disinfection systems.
- Do not use saliva or anything other than the approved solutions to wet your lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying will damage your lenses. Follow the lens care directions for Care for a Dried Out Lens if your lens surface does become dry (dehydrated).
- If your lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens must move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, immediately contact your eye care practitioner.
- Always wash and rinse your hands, and dry with a lint-free towel, before you handle your lenses. Eye irritation may result if cosmetics, solutions, soaps, creams and deodorants come in contact with your lenses and if the lenses are contaminated by infectious or noninfectious dirt.
- Avoid using aerosol products such as hair spray while wearing your lenses. If sprays are used, keep your eyes closed until the spray has settled.
- Fluorescein, a yellow dye, should not be used while the lenses are on your eyes. The lenses absorb this dye and become discolored. Whenever your eye care practitioner does use fluorescein in your eyes, your eyes should be flushed with a sterile normal saline solution, and you should wait at least one hour before replacing the lenses. Too early replacement may allow the lenses to absorb residual fluorescein irreversibly.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Do not swim with your lenses in place.
- Never use tweezers or other tools to remove your lenses from the lens container. Pour the lens into your hand.
- Do not touch the lens with your fingernails.
- Always inform your doctor that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to ensure eye health. Check with your eye care practitioner.
- Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly.
- Certain medications such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those 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, this 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 medication is being used.

## ADVERSE EFFECTS (PROBLEMS) AND WHAT TO DO

The following problems may occur:

- eye pain.
- eyes sting, burn or itch (irritation).
- comfort is less than when lens was first placed on eye.
- feeling of something in the eye (foreign body, 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.
- change in sensitivity to light (photophobia).
- feeling of dryness.

If you notice any of the above symptoms, REMOVE YOUR LENSES.

- If the discomfort or problems stops, then look closely at the lens.
- If the lens has dirt, an eyelash or other foreign body on it, or the problems stops, clean, disinfect and reinsert the lens.
- If the lens is in any way damaged, DO NOT put the lens back on the eye. Discard the lens.

If the above symptoms continue after removal of the lens or upon reinsertion of a lens or upon insertion of a new lens, the new lenses should be removed immediately and the patient should immediately contact his eye care practitioner or a physician, who must determine the need for examination, treatment or referral without delay. A serious condition such as infection, corneal ulcer, corneal vascularization or iritis may be present, and may progress rapidly. Less serious reactions, such as abrasions, epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications.

## EDGE III® (Polyacon) Soft (hydrophilic) Contact Lenses PACKAGE INSERT

**IMPORTANT:** Please read carefully and keep this information for future use

Symbol	Description
	<b>CAUTION:</b> Federal (U.S.A.) Law restricts this device to sale by, or on the order of a licensed practitioner.
	See Instruction Leaflet
	Use by date (expiration date)
	Batch code
	Sterile using steam heat

## VISION CORRECTION USE

- EDGE III Thin (polyacon) contact lenses
- EDGE III (polyacon) contact lenses
- EDGE III PRP XT (polyacon) contact lenses
- EDGE III PRP (polyacon) contact lenses

## DESCRIPTION:

The EDGE III (polyacon) soft contact lens is a soft, hemispherical shell which covers the cornea and may cover a portion of the adjacent sclera. The polyacon material is a hydrophilic polymer of 2-hydroxyethyl methacrylate cross-linked with ethyleneglycol dimethacrylate. When fully hydrated in 0.9% sodium chloride solution the composition of the lens is 62% polyacon and 38% water by weight. The refractive index is 1.43 and light transmission is greater than 97% for the visible light spectrum with powers ranging from -20.00 to +35.00 diopters. Lenses tinted for visibility purposes are tinted with the following color additive: 7, 16-dichloro-6, 15-dihydro-5,9,14,18-anthrazinetrone.

• Clinical studies have demonstrated that contact lenses manufactured from the polyacon lens material are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in this lens material.

• When selecting appropriate parameters, the eye care practitioner must consider all factors that affect lens performance and ocular health. The potential impact of these factors must be weighed against the patient's needs; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored.

The CooperVision EDGE III PRP XT and EDGE III PRP contact lenses have the same design and composition as the CooperVision Zero 6 tinted contact lenses except that, the Zero 6 lens utilizes a clear periphery full iris masked visibility tint to enhance patient handling.

## ACTIONS

In its hydrated state the EDGE III (polyacon) soft contact lens is soft and pliable. When placed on the human cornea, the lens acts as a corrective refracting medium to focus light rays on the retina.

## INDICATIONS (USES):

Daily Wear (less than 24 hours while awake)

The EDGE III (polyacon) soft contact lens is indicated for daily wear for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes who are myopic or hyperopic. The lenses may be worn by persons who may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

## CONTRAINDICATIONS (Reasons Not to Use):

The EDGE III (polyacon) soft contact lens is contraindicated in the presence of any of the following conditions:

- Inflammation in the anterior chamber of the eyes.
- Active disease, injury or abnormality affecting the cornea, conjunctiva or eyelids.
- Microbial infection of the eye.
- Insufficiency of lacrimal secretion.
- Corneal hypoesthesia.
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- Use of a medication that is contraindicated, including eye medications.
- Patient history of recurring eye or eyelid infections including sties, or of adverse effects associated with contact lens wear, or 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 an adverse working or living environment, to understand or comply with any warnings, precautions, restrictions, or directions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which must be used to care for the lens.
- Patients who require only vision correction and who would not, or could not, adhere to a recommended care system for lenses, or who are unable to place and remove lenses should not be provided with them.
- Incomplete healing following eye surgery.

## WARNINGS

**PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your lenses and lens care products. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**

To minimize these risks, strict compliance with the lens care regimen including cleaning of the lens case is needed.

Since eye injury can develop rapidly, it is most important that patients be instructed in the possible signs or symptoms of problems and the need to remove the lens and be examined by the prescribing eye care practitioner or a corneal specialist immediately if they experience any symptoms such as those listed below under Adverse Effects. (Practitioners examining patients presenting such symptoms should see below FITTING GUIDES AND PATIENT INFORMATION BOOKLETS).

All contact lens wearers must see their eye care practitioner as directed.

**Ulcerative Keratitis:** The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn 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 a regular periodic lens removal and disinfection or cleaning by the patient; contamination of lens care products poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits, damage to the lens; improper fitting; length of wearing time;

Serious corneal damage may result from wearing a lens which has been soaking in a conventional hard contact lens solution containing preservatives and chemicals which should not be used with soft hydrophilic contact lenses.

Eye irritation may occur within a short time after putting on a hypertonic lens. Removal of the lens will relieve the irritation.

Rainbows or halos around objects, or blurring of the vision, may occur if the lenses are worn continuously for too long a time. Removal of the lenses for a period of at least one hour generally relieves these symptoms.

#### FITTING INFORMATION

The EDGE III (polymacon) Fitting Guide provides detailed fitting information for contact lenses. Conventional methods of fitting soft contact lenses apply to this lens. When lenses are dispensed for vision correction, the patient must be supplied with appropriate instructions for wearing, removal and replacement of lenses. The patient must fully understand all handling and lens care instruction. In



addition, it is very important for the eye care practitioners to give the patient the Patient Information booklet and review it with the patient. Copies of Fitting Guides and Patient Information Booklets are available from:

711 North Road  
Rochester, NY 14623  
(800) 341-2020

#### WEARING SCHEDULE

##### Daily Wear (Less than 24 hours, while awake)

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently. The wearing schedule and replacement schedule should be determined by the eyecare practitioner.

There may be a tendency for the daily wear patient to overwear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care practitioner. The wearing schedules chosen by the eye care practitioner should be provided to the patient.

Care must be taken on the initial visit to ensure that the patient is supplied with the recommended heat disinfection or chemical disinfection accessory products and fully understands all care and handling instructions for the lenses. As with any contact lens, regular follow-up visits are necessary to ensure patient health and compliance with instructions.

#### MAXIMUM WEARING TIME

Day	Continuous Hours
1	4
2	6
3	8
4	10
5	12
6	14
7	All Waking Hours*

\* WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

#### LENS CARE

##### CLEANING AND DISINFECTING

The EDGE III (polymacon) contact lens must be BOTH cleaned and disinfected daily. One procedure does not replace the other. CLEANING is necessary to remove mucus and film from the lens surface. This can be accomplished by using a recommended daily cleaner. Excessive deposits may damage the lens; therefore, if this occurs, evaluation of the lens care procedure should be made. Cleaning with a recommended enzymatic contact lens cleaner, on a weekly basis, is recommended to remove and prevent buildup of protein deposits from the constituents normally found in tears.

DISINFECTING with a recommended thermal (heat) disinfecting unit and recommended saline solution has been tested microbiologically and shown to be an effective disinfection procedure for the polymacon contact lens.

If heat disinfection is used, the EDGE III (polymacon) contact lens must be cleaned with a recommended daily cleaner, each day. Fresh recommended sterile saline solution must be used for storing the lenses. The lens storage case must be emptied and are filled with fresh solution each time the lens is stored CooperVision, A CooperVision Company strongly recommends the use of a commercially prepared sterile saline solution.

Chemical disinfection with recommended disinfecting solutions has been tested microbiologically and shown to be an effective disinfection procedure for the polymacon contact lens. If chemical disinfection is used, the EDGE III (polymacon) contact lens must be cleaned and rinsed with a recommended daily cleaner and a recommended rinsing solution. This must be done daily. The lens container must be emptied and refilled with fresh recommended disinfecting solution prior to disinfecting the lens. Fresh disinfecting solution must be used each time the lens is disinfected and stored.

Chemical disinfection may also be accomplished using a hydrogen peroxide system. If this method is used, the lenses must be both cleaned and disinfected daily. For effective cleaning, disinfection, and storage, follow the instructions noted on the package labeling for this system.

#### GENERAL LENS CARE (To Clean, Rinse, Disinfect Your Lenses)

##### BASIC INSTRUCTIONS

- Always wash and rinse your hands, and dry with a lint-free towel, before handling your contact lenses.
- Use only the lens care system, either heat or chemical (including hydrogen peroxide), recommended by your eye care practitioner. Chemical disinfection solutions should not be used with heat, unless indicated on the product label for use with both heat and chemical disinfection systems.
- Carefully read your Wearer's Guide booklet for details.
- Your lenses must be BOTH cleaned and disinfected each time you remove them. CLEANING is necessary to remove mucus and film from the lens surface. DISINFECTING is necessary to destroy harmful germs.
- Clean and rinse one lens first (always the same lens first to avoid mix-ups) and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- Disinfect your lenses using the system which your eye care practitioner has recommended.
- To store your lenses, disinfect and leave them in the closed/unopened case until ready to wear.
- If the lenses have been stored in the unopened case for more than 24 hours, disinfect immediately before wearing or at least once a week. Put fresh solution inside the lens chambers, completely covering the lenses, before disinfecting.
- To prevent contamination and to help avoid serious eye injury, the lens storage case must be thoroughly rinsed once a week (or as necessary, for patients on an extended wear schedule) with

fresh rinsing solution, and left open to air dry. Do not use soap or detergent to wash the lens storage case.

To assure proper lens care and handling, each EDGE III (polymacon) contact lens patient MUST BE supplied with recommended cleaning and disinfection accessory products along with the EDGE III (polymacon) Contact Lens Wearer's Guide.

#### SOLUTIONS - HEAT

When utilizing a heat disinfection method for the cleaning, disinfection, and storage of EDGE III (polymacon) contact lenses, use recommended accessory products.

#### SOLUTIONS - CHEMICAL (NOT HEAT)

When utilizing a chemical disinfection method for the cleaning, disinfection, and storage of EDGE III (polymacon) contact lenses, use recommended accessory products.

The eyecare practitioner should recommend a care system that is appropriate for these contact lenses. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

All solutions that have been recommended for use with EDGE III (polymacon) contact lenses must be used according to the manufacturer's complete instructions.

#### THERMAL (HEAT) LENS DISINFECTION

- Fill the lens storage case with fresh saline solution.
- Clean and rinse each lens thoroughly.
- Place each lens in the correct chamber (right or left) of your lens storage case filled with saline solution; be sure the lens is completely covered with solution.
- Close the lens storage case tightly.
- Place the lens storage case in the recommended heat disinfection unit.
- Disinfect according to the directions for operation of the heat disinfection unit.
- After disinfection, store the lenses in the unopened lens storage case.
- Allow lenses to cool before handling.

#### ALTERNATIVE METHOD FOR THERMAL (HEAT) LENS DISINFECTION

- If the thermal (heat) disinfection unit is not available, place the storage case containing the lenses and saline solution in a pan of boiling water for 10 minutes (at altitudes above 7,000 feet, boil for 15 minutes).
- Remove the pan from the heat and allow to cool for 30 minutes.
- Use of the recommended thermal (heat) disinfection unit must be resumed as soon as possible.

#### CHEMICAL (NOT HEAT) LENS DISINFECTION

- Fill both chambers of the lens storage case with fresh disinfecting solution.
- Remove and handle one lens at a time.
- Clean and rinse the lens thoroughly.
- Place the lens in the appropriate chamber of the lens case, making sure the lens is completely covered with solution.
- Firmly tighten the appropriate cap.
- Repeat the above procedure with the other lens.
- To disinfect your lenses, leave them in the solution as specified in its labeling.
- THOROUGHLY RINSE YOUR LENSES WITH RINSING SOLUTION BEFORE APPLYING AND WEARING.

Chemical disinfection may also be accomplished using a hydrogen peroxide system. For effective lens care, follow the instructions noted on the package labeling for this system.

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

- Always keep the lens completely covered in a recommended storage solution when the lens is not being worn, to prevent the lens from drying out.
- If a soft (hydrophilic) contact lens is left exposed to the air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply sterile saline before handling.

#### TO REWET YOUR LENS:

- Handle a dried out lens with care.
- 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 the rehydrated lens after using a recommended lens care system.
- If after soaking, the lens does not become soft, the lens should not be used until examined by the eye care practitioner.

#### CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended rinsing or lubricating solution. Wait until the lens begins to move freely on your eye before removing it, if nonmovement of the lens continues, do not try to remove the lens. Immediately consult your eye care practitioner.

#### HOW SUPPLIED

Each sterile lens is supplied in a lens container with 0.9% buffered sterile saline. The lens container is marked with the base curve or series, dioptic power(s), diameter, manufacturing lot number, expiration date of the lens.



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