EDGE III BIOMEDICS 38 (polymacon)
HYDROPHILIC CONTACT LENSES
Package Insert

IMPORTANT:

Please read carefully and keep this information for future use.

Symbol	Description
	**CAUTION:** 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)
LOT.	Batch code
	Sterile using steam heat

VISION CORRECTION USE
EDGE III BIOMEDICS 38 (Polymacon) contact lenses.

DESCRIPTION:

The EDGE III BIOMEDICS 38 (polymacon) contact lens is for use in the EDGE III BIOMEDICS 38 Scheduled Replacement Program or Disposable Program.

In the Scheduled Replacement Program, the lens wearing time is prescribed by the practitioner from 1 to 7 days/6 nights. The lens needs to be removed before the replacement time period has elapsed and the lens must be cleaned and disinfected prior to replacing it back on the eye. These lenses should be discarded and replaced with new lenses according to the schedule prescribed by the eyecare practitioner.

In the Disposable Program, the lens wearing time is prescribed by the practitioner from 1 to 7 days/6 nights. Patients are instructed to dispose of the lenses at each removal and to use lens care products only on an emergency basis.

All EDGE III BIOMEDICS 38 (polymacon) contact lenses are available as spherical lenses. These lenses are hemispherical flexible shells of the following dimensions:

Chord Diameter:	12.5 mm to 18.0 mm
Center Thickness:	0.03 mm to 1.0 mm depending on power
Inside Spherical Radius:	6.5 mm to 10.8 mm
Powers:	+20.00 to -20.00 D (daily wear) plano to -10.00 D (extended wear)

The lens material, polymacon, is a hydrophilic polymer of 2-hydroxyethyl methacrylate cross-linked with ethyleneglycol dimethacrylate (62.0%) and water (38.0%).

The physical properties of the lens are:

Refractive Index:	1.43
Surface Character:	Hydrophilic
Water Content:	38.0%
Oxygen Permeability (Dk)*:	8.4×10^{-11} (cm2/sec)ml 0_2 /ml x mm Hg at 35°C)
Light Transmittance:	90% to 98% depending on tint type.

*Method for determination is the Fatt Method.

The EDGE III BIOMEDICS 38 (polymacon) contact lenses are tinted using the following color additives: 16, 17-Dimethoxydinaphtho (1,2,3-cd: 3',2',1'-1m) perylene-5,10-dione (aqua tinted lens); 7, 16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone (sapphire lens); N.N' (9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide and 16,17-Dimethoxydinaphtho (1,2,3-cd: 3',2',1'-1m) perylene-5, 10-dione (emerald tinted lens); 16,23-Dihydrodinaphtho (2,3-a:2',3'-i) naphth (2',3':6,7) indolo (2,3-c) carbazole-5,10,15,17,22,24-hexone and 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone (smoky quartz tinted lens). Lenses tinted for visibility purposes are tinted with the following color additive: 7, 16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.

EDGE III BIOMEDICS 38 (polymacon) contact lenses, are tinted from edge to edge for visibility purposes and have a visible light transmittance of ~~a~~ approximately 90%.

Cosmetic tinted EDGE III BIOMEDICS 38 (polymacon) contact lenses are tinted in an annular pattern, providing a clear optic zone. The material has a visible light transmittance greater than 97% through the untinted portion of the lens. The lenses are tinted in any one of the following lens colors: Aqua, Sapphire, Emerald and Smoky Quartz.

The Ocular Sciences EDGE III BIOMEDICS 38 contact lens has the same design and composition as the Ocular Sciences Hydron Zero 4 tinted contact lens except that the Zero 4 lens utilizes a clear periphery full iris masked visibility tint to enhance patient handling.

ACTIONS:

When placed on the human cornea, the hydrated lens acts as a corrective refracting medium to focus light rays on the retina.

The tinted EDGE III BIOMEDICS 38 (polymacon) contact lenses may act to enhance or appear to alter the color of the eye or mask scarred or disfigured corneas or, in the case of visibility tinted lenses, allow the lens to become readily visible to the wearer when not on the eye.

INDICATIONS:

Daily Wear:
EDGE III BIOMEDICS 38 (polymacon) contact lenses are indicated for the correction of visual acuity in aphakic and non-aphakic persons with nondiseased eyes that are myopic or hyperopic and may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

Extended Wear:

EDGE III BIOMEDICS 38 (polymacon) contact lenses are indicated for the correction of visual acuity in non-aphakic persons with nondiseased eyes that are myopic and may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

The lenses may be prescribed for either daily wear or for extended wear from 1 to 7 days between removals for disposal in the Disposable Lens Program or cleaning and disinfection in the Scheduled Replacement Program, as recommended by the eyecare practitioner (See the "WARNINGS" section with reference to the relationship between the lens wearing schedule and corneal complications).

CONTRAINDICATIONS (Reasons Not To Use):

EDGE III BIOMEDICS 38 (polymacon) contact lenses are contraindicated when any of the following conditions exist:

- 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.
- 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.

WARNINGS:

Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. Therefore, after a thorough eye examination, including appropriate medical background, patients must be fully apprised by the prescribing practitioner of all the risks associated with contact lens wear. To minimize these risks, the need for strict compliance with the care regimen including cleaning of the lens case, if the patient is on the Scheduled Replacement Program, wearing restrictions, wearing schedules, and follow-up visit schedule must be emphasized to the patient. (See the considerations listed under Contraindications and Precautions.)

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 the applicable FITTING GUIDES AND PATIENT INFORMATION BOOKLETS).

Extended Wear: 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; and the presence of ocular debris or environmental contaminants. Additionally, smoking increases the risk of ulcerative keratitis in 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 poymegathism, which require consideration of discontinuation of lens wear.

The reversibility of endothelial effects of contact lens wear has not yet been established. As a result, practitioner's views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods from 1 to 7 days/6 nights with specified intervals of no lens wear for certain patients with follow-up visits, and in the case of the Scheduled Replacement Program, with a proper care regimen. Some practitioners also recommend frequent replacement of lenses at intervals such as one to two weeks.

PRECAUTIONS:

In prescribing contact lenses, the Precautions should be carefully observed. It is also strongly recommended that the practitioner review with the patient the appropriate Patient Information Booklet (either the Scheduled Replacement or Disposable Lens Patient Information Booklet) available from Ocular Sciences, Inc. prior to dispensing the lenses and assure that the patient understands its contents.

In the Scheduled Replacement Program, in the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and cleaned and disinfected before reinsertion. If the lens becomes dehydrated, follow the lens care directions for Care for a Dehydrated Lens.

In the Disposable Program, EDGE III BIOMEDICS 38 (polymacon) contact lenses are intended to be disposed of once they are removed form the patient's eye. Therefore, it is important that patients be instructed to always have a pair of replacement lenses available. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens. If replacement lenses are not available, the patient should refer to the emergency lens care directions in the Patient Information Booklet.

Contact lens wear may not be suitable for certain occupations, or, in other instances, may require eye protection equipment.

Environmental fumes, smoke, dust and vapors, and windy conditions, must be avoided, in order to minimize the chances of lens contamination or physical trauma to the cornea.

In the Scheduled Replacement Program, or in the event of Emergency Lens Care in the Disposable Program; chemical disinfection solution may not be used with heat unless specifically indicated in the labeling for heat and chemical disinfection.

In the Scheduled Replacement Program, or in the event of Emergency Lens Care in the Disposable Program, Ocular Sciences, Inc. recommends that sterile solutions be used in the soft lens care system. Sterile non-preserved solutions should be used if the patient is allergic to preservatives. When used, sterile non-preserved solutions must be discarded after the time specified in their label directions.

Eye injury from irritation or infection and damage to lenses may result if cosmetics, lotions, soaps, creams, hair sprays or deodorants come in contact with lenses.
Eye injury from irritation or infection may result from lens contamination.

Tweezers or other tools should not be used by patients to remove a lens from the lens container. The lens should be poured into the hand.

Patients should be instructed on and demonstrate the ability of prompt removal of the lenses.

Fluorescein should not be used while the lenses are on the patient's eye. The lenses absorb this dye and become discolored. Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in-eye use; and a new lens should be reinserted only after at least one hour.

A lens must move freely on the eye for a proper fit. For further information, see the EDGE III BIOMEDICS 38 (polymacon) contact lenses Fitting Guide.

Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing, and Practitioners should conduct early and frequent follow-up examination to determine ocular response to extended wear.

In the Scheduled Replacement Program, or in the event of Emergency Lens Care on the Disposable Program: After removal of the lenses from the lens case, to prevent contamination and to help avoid serious eye injury, always empty and rinse lens case with fresh rinsing solution and allow 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.

The patient should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eyecare practitioner before using any medication in the eye.

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.

The patient who is prescribed EDGE III BIOMEDICS 38 (polymacon) contact lenses on a daily wear schedule should be cautioned to remove the lenses before sleeping.

ADVERSE EFFECTS:

The following symptoms 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.

The patient should be instructed that if any of the above symptoms occur:

- Immediately remove the 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 in the Scheduled Replacement Program; or discard the lens and replace it with a new lens from the EDGE III BIOMEDICS 38 (polymacon) contact lens container, if in the Disposable Wear Program.

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.

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS:

The EDGE III BIOMEDICS 38 (polymacon) contact lenses 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 appropriate Patient Information booklet (either Scheduled Replacement or Disposable Patient Information Booklet) and review it with the patient. Copies of Fitting Guides and Patient Information Booklets for EDGE III BIOMEDICS 38 (polymacon) hydrophilic contact lenses are available from:

CooperVision

711 North Road
Scottsville, NY 14546, U.S.A.

WEARING SCHEDULES:

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.

Daily Wear: 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. These lenses may be worn in the Scheduled Replacement Program.

Extended Wear: (Greater than 24 hours, or while asleep) The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Ocular Sciences, Inc. recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then the gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear in order to determine corneal response. The lens must be removed, cleaned and disinfected or disposed of and replace with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the WARNINGS Section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care practitioner.

LENS CARE DIRECTIONS:

When lenses are dispensed, the patient must be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care practitioner should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing scheduled and care system selected by the practitioner, the specific instructions for such products, and the particular characteristics of the patient.

Scheduled Replacement Program: For complete information concerning the care, cleaning and disinfecting of contact lenses refer to the Patient Information Booklet (for use in a Scheduled Replacement program).

Disposable Wear Program: For complete information concerning emergency lens care, refer to the Patient Information Booklet for Disposable Wear.

CARE FOR A DEHYDRATED LENS:

Disposable Wear Program: If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. Dehydrated lenses should be disposed of and not rehydrated. Therefore, it is important that the patient always have a pair of replacement lenses available.

Scheduled Replacement Program: If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply sterile saline before handling.

Eyecare practitioners should review the following information on rehydrating 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 the rehydrated lens 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) 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 removing it. If nonmovement of the lens continues after several minutes, the patient should be instructed to immediately consult the eyecare practitioner.

PRACTITIONERS FITTING SETS:

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

HOW SUPPLIED:

Each EDGE III BIOMEDICS 38 (polymacon) contact lens is supplied sterile in a container with a 0.9% buffered saline solution. Several lens containers are packaged in a multi-pack, both of which are marked with the manufacturing lot number of the lens, the diameter, the dioptric power, the lens tint, the base curve or series, and the expiration date.

Manufacturer:

CooperVision

CooperVision Caribbean Corporation
500 Road 584, Lot 7
Amuelas Industrial Park
Juana Diaz, PR 00795, U.S.A.

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