

Cooper Prosthetic Lens

(polymacon)
Soft (Hydrophilic) Contact Lenses

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.

CAUTION – Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner.

DESCRIPTION

The **Cooper Prosthetic Lens** (polymacon) Soft (hydrophilic) Contact Lenses are available as spherical lenses. The lens material, polymacon, is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) which is cross linked with ethyleneglycol dimethacrylate. When hydrated, the lens consists of 62.0% HEMA and 38.0% water by weight when immersed in normal saline. The lenses are made by modifying the uncolored polymacon lens by affixing a colored pigment on that portion of the front surface that corresponds to the iris. The colored pigments consist of carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide.

Cooper Prosthetic Lenses are hemispherical shells with the following dimensions:

Diameter:	14.0mm to 15.0mm
Base Curve:	8.0mm to 9.5mm
Center Thickness:	0.05mm to 0.40mm (varies with power)
Lens Powers:	-20.00 to +20.00D

Call our Customer Service department at (800) 341-2020 for current availability

The physical/optical properties of the **Cooper Prosthetic Lenses** are:

Refractive Index:	1.43
Light Transmittance:	>90% (open pupil)
Surface Character:	Hydrophilic
Water Content:	38%
Oxygen Permeability:	8.0×10^{-11} (cm ² /sec) (ml O ₂ /ml x mmHg) at 35°C

(Fatt method for determination of oxygen permeability)

ACTIONS

When placed on the cornea in its hydrated state, the **Cooper Prosthetic Lens** acts as a refracting medium to focus light rays on the retina.

INDICATIONS (USES)

Cooper Prosthetic Lens is indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons that may exhibit astigmatism up to 2.00 diopters that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE **Cooper Prosthetic 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 the **Cooper Prosthetic Lens**.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

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

- ❖ Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's directions and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- ❖ 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 the risk of serious adverse reactions is increased when these lenses are worn overnight.
- ❖ **The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use.** This risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case.
- ❖ Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- ❖ If a patient experiences **eye discomfort**, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners:

Due to the small number 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.

- Aphakic patients should not be fitted with **Cooper Prosthetic Lens** 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 this dye and become discolored. Whenever fluorescein is used in 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:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 - Never use solutions recommended for conventional hard contact lenses only.
 - Chemical disinfection solutions should not be used with heat unless specifically indicated on the product labeling for use in both heat and chemical disinfection.
 - Always use **fresh, unexpired** lens care solutions.
 - Always follow directions in the package inserts for the use of contact lens solutions.
 - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may damage the lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.
- 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 nonmovement 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, deodorants, 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 contact lenses with the fingers or hands if the hands are not free of foreign materials, as lens damage may occur.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instructions for Prosthetic contact lenses and those prescribed by the eye care practitioner.

- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- 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, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Feeling that something is in the eye such as a foreign body or 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 problem stops, then look closely at the lens. If the lens is in any 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 **Cooper Prosthetic Lens**. For a detailed description of the fitting techniques, refer to the **Cooper**

Prosthetic Lens Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
711 North Road
Scottsville, NY 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 overwear 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.

The wearing schedule and replacement schedule for **Cooper Prosthetic Lens** should be determined by the eye care practitioner based upon the patient's physiological eye condition, since each individual's response to contact lenses varies.

DAILY WEAR: (less than 24 hours, while awake). The **maximum** suggested wearing time is:

Day	Hours
1	6
2	8
3	10
4	12
5	14
6	all waking hours

Studies have not been completed to show that **Cooper Prosthetic Lens** (polymacon) Soft (hydrophilic) Contact Lenses are safe to wear while sleeping.

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.

General Lens Care: (To **First Clean** and **Rinse**, Then **Disinfect** Lenses)

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh, unexpired** lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care systems **unless indicated on solution labeling**.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting. Do not put lenses in the mouth.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning **and rinsing** are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of enzyme or

any cleaning solution does not substitute for disinfection.

- The eye care practitioner should recommend a care system that is appropriate for Cooper Prosthetic Lens 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.

THERMAL (HEAT) DISINFECTING METHOD

- After cleaning and thoroughly rinsing the lenses with the recommended solutions, prepare the empty lens storage case. To keep the lenses wet during disinfecting, use the solution that is recommended by the lens manufacturer or eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.
- Put the lens storage case into the disinfecting unit and follow the disinfecting unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

EMERGENCY (ALTERNATE) METHOD FOR THERMAL (HEAT) DISINFECTING

- If a heat disinfecting unit is not available, please place the tightly closed storage container which contains the lenses into a pan of already boiling water. Leave the closed lens case in the pan of boiling water for at least 10 minutes. (above an altitude of 7,000 feet, boil for at least 15 minutes). Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfecting of the lens.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

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 care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.**

- Leave the lenses in the unopened storage case until ready to put on the eyes.
- CAUTION:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement in the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING

Enzymatic cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed by regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation. Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and rinsed with solutions 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 **Cooper Prosthetic Lens** is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline solution before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storage solution for at least one hour until it returns to a soft state.
- Clean the lens first, then disinfect the rehydrated lens using a recommended lens care system.

If after soaking, the lens does not become soft, if the surface remains dry, the lens **should not be used unless it has been examined by the eye care practitioner**.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2-3 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 nonmovement of the lens continues more than 5-10 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 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 sterile buffered isotonic saline solution. The blister pack is labeled with the base curve, diameter, dioptric power, tint, manufacturing lot number, and expiration date of the lens.

Do not use if the vial or crimp seal has been broken or damaged

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing any **Cooper Prosthetic Lens** or experienced with the lenses should be reported to:



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

www.coopervision.com

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