PRODUCT LABELING FOR USE IN BOTH HEAT AND CHEMICAL DISINFECTION.

Ophthalmic A is made of polymer of 2-hydroxyethylmethacrylate and 2-methacyrloyloxyethyl phosphorylcholine crosslinked with ethylene glycol dimethacrylate.

The physical properties of the lenses are:
- Refractive Index at 25°C: 1.402
- Light Transmittance: 98.2%
- Water Content: 59%
- Oxygen Permeability: Edge Corrected Method 25 x 10⁻¹¹ cm³/sec (mO2/ml x mm Hg) at 35°C as measured by 201T Permeometer connected to a curved Rehder guard ring polarographic cell

CONTRAINdications (REASOns NOT TO USE):
- DO NOT USE this contact lens when any of the following conditions exist:
  - Previously diagnosed primary Sjogren's Syndrome Tear Deficiency and Autoimmune Connective Tissue Disease which may involve secondary Sjogren's syndrome. Such conditions include rheumatoid arthritis, polymyalgia, Wegener's granulomatosis, systemic lupus erythematosus, systemic sclerosis, primary biliary cirrhosis, and mixed connective tissue disease.
  - Acute and subacute inflammation between the lens, iris, and cornea, i.e., the anterior chamber of the eye.
  - Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
  - Any active corneal infection: purulent (pus) bacterial, viral, or fungal infection.
  - Corneal hypoplasia (reduced corneal sensitivity), if not-aphakic.
  - Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
  - Allergy to any ingredient, such as thimerosal or mercury, in a solution which must be used to care for the lens.
  - Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
  - If eyes become red or irritated

WARNINGS:
- Patients were not studied who exceed the conditions characterized by any of the following diagnostic parameters:
  - Rose Bengal staining > 12 on a scale of 18
  - Fluorescein staining > 12 on a scale of 15
  - Minimum gentle dysynergy on a scale of 0-4
- Patients should be advised of the following warnings pertaining to contact lens wear:
  - **PROBLEMS WITH CONTACT LENSES AND LENS CARE SOLUTIONS COULD RESULT IN SERIOUS INJURY TO THE EYE.** It is essential that patients follow 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 ulceration, may develop 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. 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 the lenses and promptly contact his or her eyecare practitioner.

PRECAUTIONs: Special Precautions for Eyecare Practitioners:
- Due to the small number of patients enrolled in clinical investigation of the use of lenses, all refractive astigmatism, myopic and hyperopic less than or equal to 2.00D or less that does not interfere with visual acuity.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, and I lift sprays in the eyes or on the lenses. It is best to put on lenses after 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 material. Avoid wearing scratches to the lenses may occur, causing distorted vision and/or injury to the eye.
- Indications and directions in the package insert for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing, and wearing instructions in the Patient Instructions for the Proclear Contact Lens and those prescribed by the eyecare practitioner.
- Always use FRESH unexpired lens care solutions.
- Do not use saliva or anything other than the recommended solutions to wet your lenses.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- To prevent your lenses from becoming dry (dehydrated) store them completely immersed in the recommended storage solutions.
- Follow the lens care directions for Care for a Dried Out Lens if your lens surface becomes dry (dehydrated) on the eye.
- If the lens sticks (stops moving) on the eye, follow the directions on Care for a Sticking Lens to remove the lens from the eye for 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.
- Avoid the use of any irritant or irritating vapors and fumes while wearing your lenses.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- Do not use saline or anything other than the recommended solutions to wet your lenses.
- Always follow directions in the package for the use of contact lens solutions.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always consult the eye care practitioner who fit you with your contact lenses about any changes in your eye health.
- Always wear your contact lenses as directed.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, and oil lift sprays in the eyes or on the lenses. It is best to put on lenses after 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 material. Avoid wearing scratches to the lenses may occur, causing distorted vision and/or injury to the eye.

- **Adverse reactions that may occur:**
  - Eyes sting, burn, or itch (irritation) or other eye pain
  - Contraction 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
Sensitivity to light (photophobia)
Dry eyes

If the patient notices any of the above, he or she should be instructed to: IMMEDIATELY REMOVE LENSES.

If the discomfort or problem stops, look closely at the lenses. If the lenses are damaged, DO NOT put the lens back on eye. Place the lens in the storage case and contact the eye care practitioner.

If the problem persists, the lens appears damaged, and the discomfort or problem continues, DO NOT put the lens on; immediately consult an eye care practitioner.

WHEN ANY OF THE ABOVE SYMPTOMS OCCUR, A SERIOUS CONDITION SUCH AS INFECTION, ABRA-SON, CORNEAL ULCER, NEOVASCULARIZATION, OR INJURY MAY BE PRESENT. The patient should be instructed to keep 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 these contact lenses. For a detailed description of the fitting technique, refer to “Selection” in the section in the Professional Fitting Guide, copies of which may be obtained from:

CooperVision, Inc.
Attn: Regulatory Affairs
1215 Boiseavie Avenue
Norfolk, VA 23507
1-800-225-3069
www.coopervision.com

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER.

WEARING SCHEDULE: THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to overwear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, also are extremely important.

The Proclear Contact Lenses are indicated for Daily Wear. The manufacturer suggested wearing time for these soft contact lenses is:

<table>
<thead>
<tr>
<th>Days **</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<tbody>
<tr>
<td>6</td>
<td>8</td>
<td>8</td>
<td>All waking hours</td>
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*While patients who experience discomfort and related dry eye symptoms during lens wear arising from Evaporative Tear Deficiency (non-Sjogren’s only) may wear lenses with improved comfort compared to other soft (hydrophilic) contact lenses, their wearing time may be less than it would if they did not have dry eye symptoms.

Studies have not been conducted to show that these soft contact lenses are safe to wear during sleep.

LENS CARE DIRECTIONS:

Eyeecare practitioners should review with the patient lens care information: general lens care information and specific instructions on the lens care regimen recommended for the patient: The lens may be disinfected using either a heat, peroxide or chemical disinfection system. General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:
• Always clean, rinse, and dry hands before handling contact lenses.
• Always use fresh unexpired lens care solutions.
• Use the recommended system of lens care, either heat (thermal) or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and all solutions are safe for 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 lens cleaning system for cleaning the lens.
• Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and handling are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful organisms.
• Always remove, clean, rinse, enzyme (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eyeecare practitioner. The use of an enzyme cleaning solution does not substitute for disinfection.
• The eyeecare practitioner should recommend a lens care system that is appropriate for the Proclear Contact Lens. Each lens care product contains specific ingredients, and each provides different 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 instructions.
• Clean one lens (always the same lens first to avoid mixing) rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Put the lens back into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
• After cleaning, disinfect your lenses using the system recommended by 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 eyeecare practitioner for information on storage of lenses.
• After removing the lenses from the lens case, empty and rinse the storage case with solution as recommended by the lens case manufacturer; then allow lens case to dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens case manufacturer or your eyeecare practitioner.
• Eyeecare practitioners may recommend a lubricating/nigating solution which may be used to wet (lubricate) lenses while they are being stored or after handling. This may be more comfortable.
• Heat (Thermal) Lens Disinfection:
• After cleaning and thoroughly rinsing contact lenses with the recommended solutions, prepare the empty lens storage case. To keep the lenses wet during disinfection, use the solution that is recommended by the lens manufacturer and/or the eyeecare practitioner.
• Wet the lens chambers (sections) with fresh disinfection solution.
• Put each lens into its correct chamber.
• Fill the chamber of the case to the line with fresh solution. Or carefully cover the lenses.
• Tightly close the top on each chamber of the lens storage case.
• Put the lens storage case into the disinfection unit following the 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 reinserterion of the lenses, no rinsing is necessary unless the eyeecare practitioner recommends rinsing.

Chemical (Not Heat) Lens Disinfection:

Cleaning lens contacts with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.

After disinfection, carefully follow the instructions accompanying the disinfecting solution recommended by the lens manufacturer or the eyeecare practitioner.

When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations 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 require thorough rinse in fresh sterile saline solution prior to placement on the eye. The lens should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE:

Enzyme cleaning may be recommended by the eyeecare practitioner. Enzyme cleaning removes protein deposits on the lenses. These deposits are removed by the enzyme (lysozyme) protein deposit-lowering protein deposit on the lens. These deposits are removed without damaging the lens and cause irritation. Enzyme solutions: Complexes. DO NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions on the enzymatic cleaning labeling.

LENS CARE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacterial growth. Cases should be replaced at regular intervals as recommended by the lens case manufacturer and/or your eyeecare practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS:

If a contact lens is off the eye and exposed to air for 10 minutes or longer, it will become dry and brittle. Handle the lens carefully. To rewet: Place the lens in its storage case and SOAK the lens in the recommended rinsing solution. Keep the lens in the SOAK for 24 hours. Soak the lens until it returns to a soft state. Clean and disinfect the rewetted (rehydrated) lenses using the lens care system recommended by eye care practitioner. If, after soaking, the lenses do not become soft, DO NOT REWET THE LENS, but contact eye care practitioner.

CARE FOR A STICKING LENS: If the lens sticks (stays moving) on the eye, apply 2-3 drops of the recommended lubricating solution. Wait until the lens begins to move freely on eye before removing it. If non-movement of the lens continues, the patient should immediately consult 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 AND IMMEDIATELY CONTACT THE EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

Caution: The Packaging of This Product Contains Dry Natural Rubber which May Cause Allergy Reactions in Some Patients. How Supplied: Each lens is sterilized and supplied in a glass vial containing buffered saline solution. The glass vial is marked with the base curvature, diameter, power, and lens deposit number and the lens expiration date.

DO NOT USE IF THE GLASS VIAL OR CRIMP SEAL HAS BEEN DAMAGED OR BROKEN.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions should be reported to the CooperVision, Inc. Complaints Processing Program. Contact Lenses experienced or with the lenses should be reported to:

Attn: Regulatory Affairs
1215 Boiseavie Avenue
Norfolk, VA 23507 (USA)
1-800-225-3069

Rev. Date: July 2004 - Lathe

REFERENCE:
NE/industry Workshop on Clinical Trials in Dry Eyes - CLAO October 1995