

**IMPORTANT:** This package insert is effective as of April, 2003 and supersedes all prior inserts for the products described below. Please read carefully and keep this information for future use. **This package insert is intended for the eye care professional, but should be made available to patients upon request.** The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. **Copies of this Package Insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1-800-241-5999 or download from our website at [www.cibavision.com](http://www.cibavision.com).** CIBA Vision makes available a Patient Instruction Booklet that is recommended to be given to the patient.

## R Only

**CAUTION: FEDERAL (UNITED STATES) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.**

### **SPHERICAL CONTACT LENSES FOR:**

Nearsightedness (myopia), farsightedness (hyperopia), and keratoconus.

### **DESCRIPTION:**

The SoftPerm (synergicon A) contact lens is available as a spherical lens only. The SoftPerm contact lens is a rigid circular shell with a soft hydrophilic skirt, generally spherical surfaces, and the following dimensions:

Chord Diameter: 14.3 mm  
Center Thickness: 0.08 mm to 0.28 mm  
Base Curve: 6.0 mm to 10.0 mm  
Power Range: -20.00 to +20.00 Diopters

The lens material (pentasilcon P) which comprises the optical phase of the lens, is a rigid, oxygen-permeable copolymer: Poly (tertiary butyl-styrene-co-methyl-methacrylate-co-maleic anhydride-co-penta methyl disiloxanyl-methacrylate-co-1,1,1-tri-methylolpropane trimethacrylate).

The lens material which comprises the soft phase of the lens is a hydrophilic copolymer: 2-hydroxyethyl-methacrylate-co-2-methoxyethyl methacrylate-co-1,1,1-trimethylolpropane trimethacrylate.

The composite material is synergicon A.

The physical properties of the rigid optical phase of the lens are:

Specific Gravity: 1.015 at 25°C  
Refractive Index: 1.53 (Nd at 25°C)  
Light Transmittance: Min. 90%  
(in the visible range)  
Surface Character: Wettable; contact angle is 21° (CLMA method)  
Water Content: <0.2% by weight  
Oxygen Permeability:  $14 \times 10^{-11}$  (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/ml-mm Hg) (as measured with Schema Versatae Oxygen Flux Meter)

The physical properties of the soft hydrophilic phase of the lens are:

Water Content: 25%  
Surface Character: Hydrophilic  
Oxygen Permeability:  $5.5 \times 10^{-11}$  (cm<sup>2</sup>/sec) (ml O<sub>2</sub>/ml-mm Hg)  
(as measured with Schema Versatae Oxygen Flux Meter)

### **ACTIONS:**

The SoftPerm contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

### **INDICATIONS (USES):**

SoftPerm contact lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and for keratoconus. The lens may be worn by persons whose eyes exhibit astigmatism of 4.00 diopters (D) or less that does not interfere with visual acuity.

### **CONTRAINDICATIONS (REASONS NOT TO USE):**

DO NOT USE SoftPerm contact lenses if any of the following conditions exist:

- Acute or subacute inflammation between the lens, the iris and the cornea(the anterior segment of the eye).
- Any disease, other than keratoconus, which affects the cornea or conjunctiva.
- Any active corneal infection: pus (purulent), bacterial, fungal, or viral.
- Insufficient lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- Any condition that has led to extensive corneal vascularization.
- Allergy to any preservative or other ingredient present in solutions which must be used to care for SoftPerm contact lenses.
- Patient is unable to follow lens care regimen or unable to obtain assistance to do so.

### **WARNINGS:**

**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 professional's directions and all labeling instructions for proper use of lenses and lens care products. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF THE PATIENT EXPERIENCES EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, OR OTHER PROBLEMS WITH THEIR EYES, IMMEDIATELY REMOVE LENSES AND PROMPTLY CONTACT EYE CARE PROFESSIONAL.**

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that 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 storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers.

It is recommended that contact lens wearers see their eye care professional twice each year or, if directed, more frequently.

**THE PACKAGING OF THIS PRODUCT CONTAINS DRY, NATURAL RUBBER.**

### **PRECAUTIONS:**

Patient should follow the instructions below to prevent damage to eye(s) or to lens(es):

- 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 and appropriate lens design and parameters, the eye care professional 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; the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care professional.

- Before leaving the eye care professional's office, the patient should be able to promptly remove the lens(es) or have someone else available to remove the lens(es) for him/her.
- The patient should be instructed to follow the lens care system for SoftPerm contact lenses. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only lens care solutions recommended by the eye care professional, and always follow directions in the package inserts for the proper use of the contact lens solutions.
- **NEVER USE CONVENTIONAL HARD CONTACT LENS SOLUTIONS.**
- **ALWAYS USE FRESH RINSING, DISINFECTING AND STORAGE SOLUTIONS. STERILE UNPRESERVED SOLUTIONS, WHEN USED SHOULD BE DISCARDED AFTER THE TIME SPECIFIED IN THE LABELING DIRECTIONS.**
- **USE ONLY CHEMICAL (NOT HEAT) LENS CARE SYSTEMS.**
- **NEVER EXPOSE SoftPerm Contact Lenses TO HEAT.**
- **NEVER USE A CHEMICAL DISINFECTION SOLUTION WITH HEAT.**
- **DO NOT USE SALIVA OR ANYTHING OTHER THAN THE RECOMMENDED SOLUTIONS FOR LUBRICATING OR WETTING LENSES.**
- Always keep lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying may damage lenses. Follow the lens care directions under "Care for a Dehydrated Lens", if the lens surface does become dry (dehydrated).
- A lens must move freely on the eye for the continued health of the eye. If lens sticks (stops moving) on the eye, follow the recommended directions for "Care for a Sticking Lens." If after following these directions, non-movement of the lens continues, immediately consult an eye care professional.
- Always wash, rinse, and dry hands before handling lenses. Eye irritation may result if cosmetics, lotions, soaps, creams or deodorants come in contact with the lenses, or the contact lenses become contaminated by some other means.
- Avoid using aerosol products, such as hair spray, while wearing lenses. If sprays are used, keep eyes closed until the spray has settled.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever eye care professional does use fluorescein in the eyes, they should be flushed with sterile normal saline solution and wait at least one hour before replacing the lenses.

**NOTE:** There is a special type of fluorescein that can be used with your SoftPerm lenses. This special fluorescein is called Fluorexon, and is sold under the trade name of Fluoresoft by Holles Laboratories, Inc.

- DO NOT WEAR SoftPerm Contact Lenses WHILE SLEEPING.
- Avoid harmful or irritating vapors and fumes while wearing lenses.
- Do not swim with lenses in place.
- Never use tweezers or other tools to remove lens(es) from the lens storage case. Pour the lens into hand, or touch it with fingertip - it will adhere.
- Do not touch the lens with fingernails.
- Always inform the doctor (health care professional) about being a contact lens wearer.
- Always consult the eye care professional before using any medication.
- Always inform an employer of being a contact lens wearer. Some jobs may require that the patient not wear contact lenses, or that the patient use eye protection equipment.
- As with any contact lenses, follow-up visits are necessary to assure continued ocular health. It is recommended that contact lens wearers see their eye care professional twice each year, or, as recommended by the eye care professional.
- SoftPerm contact lenses must **never** be immersed in any solution containing the preservative chlorhexidine as this may seriously interfere with lens wettability and comfort on the eyes.

### ADVERSE REACTIONS

#### (PROBLEMS AND WHAT TO DO):

The following problems may occur when wearing contact lenses: eyes sting, burn or itch (irritation or allergic reaction)

- Comfort is less than when the contact lens was first placed on the eye
- Feeling of something in the eye (foreign body, scratched area or abrasion)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

IF THE PATIENT NOTICES ANY OF THE ABOVE PROBLEMS, IMMEDIATELY REMOVE THE LENSES.

- If the discomfort or problem stops, carefully examine the contact lens for damage and/ or debris.
- If the lens appears damaged, DO NOT put the lens back on the eye. Place the lens in a storage case and contact the eye care professional.
- If the lens appears undamaged but has dirt, an eyelash, or other foreign body on it, thoroughly clean, rinse and disinfect the lens; then reapply it to the eye.
- If the discomfort or problem persists, DO NOT put the contact lens back on the eye. Store the lens in the recommended storage solution and IMMEDIATELY consult the eye care professional. DO NOT place any contact lens on the affected eye until instructed to do so by the eye care professional.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. Corneal thickening or abrasion may occur if the lens does not fit properly or if the wearing time is excessive. Professional identification of the problem and prompt treatment are necessary to avoid serious ocular complications.

FITTING Conventional methods of fitting soft contact lenses do not apply to SoftPerm contact lenses. For a detailed description of the fitting technique, refer to the SoftPerm Professional Fitting Guide available from:

CIBA Vision  
11460 Johns Creek Parkway  
Duluth, Georgia 30097

### ADVERSE EFFECT REPORTING:

If a patient experiences any adverse effects associated with the use of SoftPerm lenses, eye care professionals please notify: CIBA Vision Corporation, Technical Consultation, 1-800-241-7468.

### WEARING SCHEDULE:

THE WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PROFESSIONAL. Patients tend to overwear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular examinations at scheduled intervals, as determined by the eye care professional, are also extremely important.

DAILY WEAR - (less than 24 hours, while awake)

Day 1	Four hours continuous wear
Day 3	Five hours continuous wear
Day 5	Six hours continuous wear
Day 7	Seven hours continuous wear
Day 9	Eight hours continuous wear
Day 11	Nine hours continuous wear
Day 13	All waking hours

### GENERAL LENS CARE:

#### Basic Instructions: (To Clean Rinse and Disinfect Lenses)

- Always wash hands using an additive-free soap, rinse thoroughly, and dry hands with a lint-free towel before handling contact lenses.
- Use a hydrogen peroxide (3% ophthalmic) solution for lens care.
- Carefully read the Patient Instruction Booklet for details.
- Lenses must be BOTH cleaned and disinfected every time they are removed. CLEANING is necessary to remove mucous and film from the lens surface. DISINFECTING is necessary to destroy harmful germs.
- Remove one lens first (always the same lens first to avoid mix-ups) and place the lens into the correct chamber of the lens storage case. Repeat this procedure for the second lens.
- Clean and disinfect lenses using the system recommended by the eye care professional.
- To store lenses, clean, disinfect, neutralize, rinse, and leave them in the closed/ unopened lens storage case until ready to wear. If the lenses have been stored in the unopened lens storage case for more than 24 hours, repeat the cleaning, disinfecting, neutralizing and rinsing procedures using fresh solutions prior to wearing the lenses.
- To prevent contamination and avoid serious eye injury, always empty and rinse the lens storage case after each use with fresh lens storage solution or hot tap water and allow it to air dry. If the storage case cannot be properly cleaned in this manner, it should be replaced. Never use soaps, detergents or other cleaning agents.
- **NOTE:** SoftPerm contact lenses cannot be thermally (heat) disinfected.

NEVER USE ANY SOLUTION CONTAINING CHLORHEXIDINE, AS THIS MAY SERIOUSLY INTERFERE WITH LENS WETTING AND COMFORT ON THE EYES.

DO NOT USE CLEANERS WITH ISOPROPYL ALCOHOL.

Never use the above solutions with heat to clean or disinfect your SoftPerm contact lens(es), as this may damage the lens(es).

CIBA Vision recommends AOSEPT Clear Care for use with SoftPerm lenses.

REFER TO THE PACKAGE INSERTS OF EACH INDIVIDUAL LENS CARE PRODUCT FOR IMPORTANT SAFETY INFORMATION AND COMPLETE DIRECTIONS.

### LENS REPLACEMENT SCHEDULE:

The eye care professional should recommend and approve a replacement schedule. CIBA Vision recommends annual replacement, or as recommended by the eye care professional.

### CARE FOR A DEHYDRATED LENS:

If the SoftPerm contact lens is off the eye and exposed to air for 30 minutes or longer, its soft skirt will become dry and brittle.

To Rewet Lens:

- Handle the lens carefully.
- Place the lens in the lens storage case and SOAK in a recommended sterile saline solution until the lens skirt returns to a soft state - at least one-half hour.
- If after soaking, the lens skirt does not become soft, DO NOT USE THE LENS, but contact the eye care professional.
- Clean and disinfect the rehydrated contact lens.

### CARE FOR A STICKING LENS:

If the lens sticks (stops moving) on the eye, apply 2-3 drops of a sterile saline solution recommended for use in eyes. Wait until the lens begins to move on the eye before removing it. If non-movement of the lens continues, immediately consult the eye care professional.

### HOW SUPPLIED:

Each lens is sterilized and supplied in a glass vial containing buffered isotonic saline. The glass vial is marked with the base curve, dioptric power, diameter, manufacturing lot number and expiration date.

### Additional Information:

For answers to questions about the SoftPerm contact lenses, contact our Professional Consultation Services at 1-800-241-7488 during regular business hours.

For additional copies of the Eye Care Professional Package Insert, Fitting Guide, and Patient Instruction Booklet, contact our Customer Service Department at 1-800-241-5999.

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