

UltraHealth™ (petrafocon A hem-larafilcon A) Contact Lenses for Daily Wear

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

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 patient instructions that pertain to the patient's prescribed lens.

DESCRIPTION

UltraHealth (petrafocon A-hem-larafilcon A) Contact Lenses are manufactured from highly permeable rigid gas permeable material (petrafocon A) and a poly-silicone hydrogel material (hem-larafilcon A). The lenses are designed to have three zones on the anterior and posterior surfaces:

Rigid Gas Permeable Material

1. The central aspherical or spherical rigid gas permeable zone.
2. The intermediate spherical zone
3. The peripheral anterior edge taper and posterior bevel soft zone.

An edge terminus smoothly joins the anterior taper to the posterior bevel.

UltraHealth Contact Lenses for hyperopia and myopia, and presbyopia are for daily wear in eyes with corneal astigmatism. The center material is a thermoset fluorosilicone acrylate copolymer derived primarily from Styrenic siloxane, aliphatic siloxane methacrylate, hexafluoroisopropyl methacrylate, hydrophilic methacrylate, cross linkers and UV blocker with a water content of <1%. The peripheral skirt material is a silicone hydrogel which is composed of aliphatic siloxane methacrylate, hexafluoro isopropyl methacrylate N, N-dimethylacrylamide and cross linkers with a water content of 33% ± 1.5%. The overall water content for the lens is 28% ± 1.8%. The lenses are available as lathe cut contact lenses with a violet tint in the rigid central material. The violet material contains D & C Violet No. 2. The silicone hydrogel skirt is clear.

Detailed Description of Fitting the UltraHealth Contact Lens

The UltraHealth should be fit such that the posterior curve of the lens clears the central corneal apex by approximately 100 microns after fitting. Increased clearance may be observed in the peripheral portion of the steepest meridian and some bearing may appear in the paracentral region of the flattest meridian. At fitting, choose the flattest skirt that allows desired clearance along with adequate movement; i.e., at least 1 mm on blink with straight-ahead gaze and with upward gaze. Some gentle bearing centrally may be observed at follow-up. If present and eye is otherwise asymptomatic (with staining) and patient has no discomfort, fit is correct.

The central rigid portion of the lens measures 8.4 mm. The transition to the peripheral spherical zone begins outside the rigid – soft junction in a seamless fashion. A posterior peripheral bevel is present and terminates at the lens edge. The lens diameter is held constant at 14.5 mm. Posterior lens-tear exchange is facilitated by a pumping action upon blinking and assisted by the minimal edge clearance provided by the skirt.

The anterior central curve is selected to provide any necessary optical power to correct spherical refractive error not corrected by the optical effect of the posterior base curve and the tear lens formed between it and the cornea. As with rigid gas permeable lenses there may be residual lenticular astigmatism uncorrected by the lenses.

UltraHealth™ Lens Parameters Available:	Overall Lens	RGP Center	Soft Skirt
Overall Diameter (D)	14.5mm		
Vault	0.05 to 0.75 mm		
Base Curve Radius- Soft Skirt			Steep, Medium and Flat
Optical Zone Width		6.0 to 6.5 mm	
Center Thickness Range		0.16 to 0.39mm	
Dioptric Powers		+25.00 to -25.00D	

Lens Properties:

LENS CHARACTERISTICS	UltraHealth™ (RGP Center)	UltraHealth™ (Soft Skirt)
Refractive Index	1.442 (Nd @ 25°C)	1.435
Luminous Transmittance (D&C Violet No. 2) (380nm to 780nm)	87%	97%
Wetting Angle (initial advance angle) (RGP Center)	34°	
Specific Gravity (RGP Center)	1.15	N/A
Hardness	76	54 Dry; 8.9 Hydrated
Oxygen Permeability †	130	84
Water Content	<1%	32%
Overall Water Content	27%	

\* Determination of the Spectral and Luminous Transmittance, ISO 8599:1994

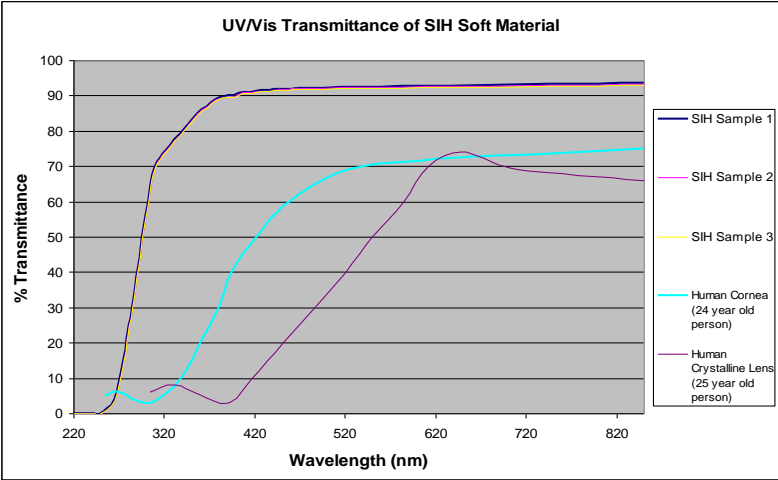
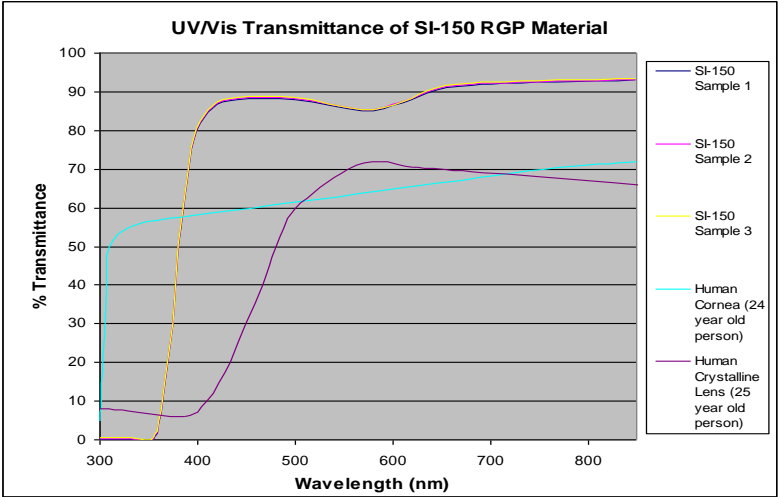
† Method for determination of oxygen permeability: ISO/DIS 9913.1 1994. Optics and Optical instruments – Contact Lenses- Part 1: Determination of oxygen permeability and transmissibility with the Fatt method. (PHEMA Standard)

ACTIONS

SynergEyes UltraHealth™ Daily Hybrid Contact Lenses act as a refracting medium to focus light rays on the retina. Transmittance of ultraviolet light through the contact lens at the thinnest lenses available (0.12mm) at power range from -20.00D to +20.00D (thinnest lenses) are as follows:

UV-A (380-315nm)  
RGP Center: 18.0%      Soft Skirt: 87.7%

UV-B (315 nm-280nm)  
RGP Center: 3.3%      Soft Skirt: 74.2%



INDICATIONS (USES)

SynergEyes UltraHealth (petrafocon A-hem-larafilcon A) Contact Lenses are indicated for use in the correction of eyes with refractive errors that include hyperopia and myopia that manifest astigmatism, in aphakic and not aphakic, and otherwise non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +20.00 and –20.00 D in eyes with astigmatism up to 6.00 D. Store lenses overnight in an FDA-approved multipurpose solution as recommended by the solution manufacturer. The lenses may be disinfected using only a hydrogen peroxide disinfecting system compatible with both silicone-hydrogel and rigid gas permeable lenses.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE SynergEyes UltraHealth Contact Lenses when any of the following conditions exist:

- Acute and sub-acute inflammations or infection of the anterior chamber of the eye.
- Any eye disease-excluding keratoconus, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- 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 that is to be used to care for contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

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 you follow your eye care practitioner's directions and all labeling instructions for proper use of your 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.
- 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 lens and promptly contact his or her eye care practitioner.

PRECAUTIONS

Special Precautions for Eye care Practitioners:

- Clinical studies demonstrated that contact lenses manufactured from the SynergEyes material are safe and effective for daily wear. Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the SynergEyes UltraHealth Contact Lens were 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.
- Patients who wear aspheric contact lenses to correct far or near vision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- When using fluorescein in the fitting evaluation of the UltraHealth Contact Lens; either high or low molecular weight fluorescein can be used.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove 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 eyes become 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.
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (NOT HEAT) lens care system. Use of a heat lens care system can warp the center of the SynergEyes UltraHealth Contact Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or tap water 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. Prolonged period of drying may damage the silicone-hydrogel lens skirt. Follow the lens care directions on *Care for a Dried Out Lens* if the lens skirt becomes 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 non-movement 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 fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instruction Booklet for SynergEyes UltraHealth contact lenses and for solutions prescribed by the eye care practitioner.
- Never wear lenses with bubbles present, or beyond the time recommended by the eye care practitioner.
- If aerosol products such as hairspray 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 (PROBLEMS AND WHAT TO DO)

Patients 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 of something 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 THEIR 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 your eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse and disinfect the lens; then reapply it.
- After reapplication of the lens, if the problem continues, the patient should IMMEDIATELY remove the contact lens and consult your eye care practitioner.
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. Keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

SUMMARY OF CLINICAL STUDY

A three month clinical study of the SynergEyes contact lens with silicone hydrogel skirt was conducted to assess safety and effectiveness for vision correction in daily wear that included subjects with nearsightedness. The study was designed to evaluate contact lens visual acuity and wearing time; and assess contact lens adverse events and loss of visual acuity.

Overall Findings:

A total of 98 subjects in which 73.2% (41/56) test subjects, and 87.1% (27/31) control subjects completed the ninety day study. The study was a prospective, unmasked, open label study in an approximate 2:1 ratio of test to control conducted at 8 investigational sites. The population demographics were similar to previous contact lens studies with a female to male gender ratio of 2.1 to 1.0. The average age of the completed and discontinued subjects was 39.1 with an age range of 18 years to 55 years of age. Nineteen (19) subjects discontinued from the study (15 test and 4 control) with the most common reason for discontinuation reported as “subject decision” for the test cohort (40%) and discomfort for the control cohort (75%). One test cohort subject was discontinued for adverse event and 1 test cohort subject was discontinued for positive slit lamp.

Safety:

A total of 5 adverse events were reported for 5 eyes during the study with 4 adverse events reported for the test cohort and 1 adverse event reported for the control cohort. Three (3) of the 5 adverse events (2 test/ 1 control) were reported as serious adverse events. Results of the slit lamp examinations showed the test cohort eyes presenting with more staining overall when compared to the control cohort examinations. All other slit lamp findings were reported a similar rates and severities when looking at the overall visit combined findings for both the test and the control cohorts. Symptoms problems and complaints were compared between the test and the control cohorts and reviewed against the baseline proportions. The test cohort eyes reported proportionately greater symptoms (1.1% for itching/burning to 16.1% for dryness) when compared to the control cohort eyes except for excessive tearing (essentially equal) and variable vision (3.6% control). Most of the differences in symptoms rates were small (3.7% or less) except for halos (8.6% test) and dryness (16.1% test).

Efficacy:

Snellen visual acuity with contact lenses remained stable throughout the study for both the test and the control cohorts. Two test and 2 control cohort eyes reported a 2 line drop of Snellen visual acuity with the contact lenses at the final visit.

Average daily wearing times were similar between the two cohort groups throughout the study.

Lens deposit and fitting evaluations were similar between the two cohorts. Lens replacements were greater in the Test lenses as compared to the control for parameter change, and the control lenses were replaced more frequently for discomfort.

FITTING

Refer to the Professional Fitting and Information Guide for detailed information on the fitting of the SynergEyes UltraHealth Contact Lens for daily wear. Copies are available from:

**SynergEyes, Inc. • 2232 Rutherford Road • Carlsbad, CA 92008 USA**  
**Telephone (USA): +1-760-476- 9410 or FAX: +1-760-476 9340**  
**www.synergeyes.com**

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wearing schedule to the level recommended by the eye care practitioner regardless of how comfortable the lenses feel. It is ideal for the patient to start with the break-in schedule recommended by their doctor. A well fit lens provides for centration and minimal movement. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear.

Patients must be cautioned; “when in doubt, take it out”. It is important that the new wearer not over wear the lens or endure a lens that has an obvious foreign body sensation. In the event of foreign body sensation, the patient should be instructed to remove the lens, clean and rinse it and re-apply the lens. If the sensation continues, the lens should not be worn.

The patient should report for follow-up evaluation at the prescribed follow up schedule. The visit is best scheduled after several hours of wear and the patient should report with the lens in place. This visit provides an excellent opportunity to evaluate lens fit, comfort and vision. Upon the absence of clinical signs and complications, the patient may be instructed to continue daily wear of the lens until the next scheduled follow-up visit.

An alternate initial daily wear schedule may be offered at the practitioner’s discretion.

Day 1	wear not to exceed 6 hours total	Day 2	6 hours
Day 3 - Day 5	8 hours	Day 6	wear as eye care practitioner allows during waking hours

LENS CARE DIRECTIONS

Eye care practitioners should review lens care directions with the patient, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

**General Lens Care (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 system of lens care, which is chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- To avoid contamination, do not use saliva or tap water or anything other than the recommended solutions (ex. non-preserved saline) for lubricating or rewetting and inserting your lenses. Do not put lenses in your 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 and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Ensure that tamper proof seal is intact prior to initial use. Do not use if tamper proof seal is broken or missing.
- Lenses should never be worn while swimming.

The lens care products listed below are recommended for use with SynergEyes UltraHealth Contact Lenses.

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Cleaning	Alcon OPTI-FREE® EXPRESS® <b>OR</b> Alcon OPTI-FREE® RepleniSH® <b>OR</b> AMO COMPLETE® Multi-Purpose Easy Rub™ <b>OR</b> Bausch & Lomb ReNu MultiPlus® Multi-Purpose <b>OR</b> CIBA VISION Clear Care® <b>OR</b> CIBA VISION AQuify® Multi-Purpose <b>OR</b> Bausch & Lomb BioTrue™
Rinsing	Alcon’s OPTI-FREE® EXPRESS® <b>OR</b> Alcon OPTI-FREE® RepleniSH® <b>OR</b> AMO’s COMPLETE® Multi-Purpose Easy Rub™ <b>OR</b> Bausch & Lomb’s ReNu MultiPlus® Multi-Purpose <b>OR</b> CIBA VISION’s AQuify® Multi-Purpose <b>OR</b> Bausch & Lomb BioTrue™
Disinfection	Alcon OPTI-FREE® EXPRESS® <b>OR</b> Alcon OPTI-FREE® RepleniSH® <b>OR</b> AMO COMPLETE® Multi-Purpose Easy Rub™ <b>OR</b> Bausch & Lomb ReNu MultiPlus® Multi-Purpose <b>OR</b> CIBA VISION Clear Care® <b>OR</b> CIBA VISION AQuify® Multi-Purpose <b>OR</b> Bausch & Lomb BioTrue™
Storage	Alcon OPTI-FREE® EXPRESS® <b>OR</b> Alcon OPTI-FREE® RepleniSH® <b>OR</b> AMO COMPLETE® Multi-Purpose Easy Rub™ <b>OR</b> Bausch & Lomb ReNu MultiPlus® Multi-Purpose Purpose <b>OR</b> CIBA VISION Clear Care®* <b>OR</b> CIBA VISION AQuify® Multi-Purpose <b>OR</b> Bausch & Lomb BioTrue™
Lubrication	AMO Blink Contacts® Lubricant Eye Drops

SupraCLENS® and Unisol® 4 are registered trademarks of Alcon Laboratories, Inc. Clear Care® is a registered trademark of Ciba Vision, Inc. Oxysept® Ultracare® Formula Peroxide Disinfection System is a registered trademark of AMO. 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 the solution manufacturer’s instructions. \*Storage in CIBA VISION Clear Care® for longer than 7 days is not recommended.

1. Clean

While the recommended care products may be approved for a “No Rub” regimen, it is recommended that moderate daily cleaning be conducted with your *SynergEyes UltraHealth* Contact Lenses. Clean one lens first (always start with the same lens first to avoid mix-ups). Place the lens, front side down, in the palm of the hand and apply several drops of the multipurpose solution. Using the index finger of the other hand, apply slight pressure in a swirling motion for the time recommended by the hydrogen peroxide solution manufacturer. **Note: Do not clean the lens by rubbing it between the thumb and index fingers, as this may cause lens warpage.**

2. Rinse

Rinse the lens thoroughly with the saline solution to remove mucus, and film from the lens surface. Place that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.

3. Disinfect

After cleaning and rinsing the lenses disinfect them by using hydrogen peroxide solution. Follow the instructions provided with the solution labeling. **Note: SynergEyes UltraHealth Contact Lenses cannot be heat (thermally) disinfected.**

4. Storage

To store lenses, disinfect and leave them in the closed case until ready to wear. Always keep your lenses completely immersed in the saline solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses.

5. Care of Your Lens Case

Contact lens cases can be a source of bacteria growth. After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or your eye care practitioner.

6. Lubricating/Rewetting Solutions

Your eye care practitioner will recommend a lubricating/rewetting solution for your use. Lubricating/Rewetting solutions can be used to rewet (lubricate) your lenses while you are wearing them to make them more comfortable.

7. Lens Deposits and Use of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of your 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 recommended care product is SupraCLENS®. The recommended frequency for use of SupraCLENS® is once every seven days (1 night per week). Carefully follow the instructions in the enzymatic cleaning labeling.

8. Care for a Sticking (nonmoving) Lens

If the lens sticks (stops moving) or cannot be removed, you should apply 5 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. To initiate movement gently push the lens upward with your index finger on the margin of the lower lid. If non-movement of the lens continues after 30 minutes, you should IMMEDIATELY consult your eye care practitioner.

9. Care for a Dehydrated Lens

The soft silicone-hydrogel portion of the *SynergEyes UltraHealth* Contact Lens may become dried out if left exposed to air while the lenses are off the eye. Rehydrate the lens by carefully placing the lens into the storage case and covering it with the saline solution. The lenses should be soaked for a minimum of five minutes prior to handling. Properly clean, rinse and disinfect the lenses prior to application on the eye.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: FLUSH EYES IMMEDIATELY WITH TAP WATER, THEN REMOVE LENSES PROMPTLY, IF POSSIBLE, AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED






Each SynergEyes UltraHealth contact lens is supplied in a sterile glass vial. The lens is shipped wet in 0.9% buffered sodium chloride solution. The vial label is marked with the central equivalent base curve radius, skirt curve radius, dioptric power, overall diameter, lot number and expiration date. In addition, the vial label will show icons for Rx Only and Sterile marks. The packing slip or invoice is marked with the central equivalent base curve radius (or vault), skirt curve radius (or skirt curve parameter), dioptric power, and lot number.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing SynergEyes UltraHealth contact lenses or experienced with the lens should be reported to:

**SynergEyes, Inc. • 2232 Rutherford Road • Carlsbad, CA 92008 USA**  
**Telephone (USA): +1-760-476- 9410 or FAX: +1-760-476 9340**  
**www.synergeyes.com**

*Manufactured and Marketed by:*  
*SynergEyes, Inc. 2232 Rutherford Road Carlsbad, CA 92008 USA*  
**P/N 70082 Rev. A**

Symbol	Definition
	For sale only by or on the order of a physician.
	Sterilized by irradiation
	Attention, see instructions for use.
	Use by Date
 45°C	Upper limit of temperature

