UltraHealth® SiH (petrafocon A hem-larafilcon A) Daily Wear Hybrid Contact Lenses for Keratoconus
CAUTION: SALE OF THIS DEVICE IS RESTRICTED TO 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 eyecare practitioner should provide the patient with patient instructions that pertain to the patient's prescribed lens.*

INTRODUCTION

SynergEyes® UltraHealth® SiH (petrafocon A larafilcon A) Hybrid Contact Lenses for Keratoconus provide refractive error correction for keratoconus when worn for daily wear. The lens center provides the optics of rigid gas permeable lenses while the silicone-hydrogel skirt provide stability. Greater attention must be directed toward fitting the lens than with essentially single parameter hydrogel lenses. The base curve of the lens is modulated to provide an optimum central lens-cornea relationship, the skirt radius is modulated to provide an optimum scleral relationship and the power of the lens is modulated to provide the desired refractive correction.

DESCRIPTION

SynergEyes UltraHealth Daily Wear Hybrid Contact Lenses are manufactured from rigid gas permeable material (petrafocon A) and SynergEyes silicone-hydrogel material (hem-larafilcon A). The lenses are designed to have at least four zones on the anterior and posterior surfaces:

RGP Material	The central aspherical or spherical zone
Poly-HEMA Material	The intermediate spherical zone The peripheral anterior edge taper and posterior bevel An edge terminus smoothly joining the anterior taper to the posterior bevel

SynergEyes UltraHealth® Daily Wear Hybrid Contact Lenses for keratoconus are for daily wear. The center material is a thermoset fluorosilicone acrylate copolymer derived primarily from Styrenic siloxane, aliphatic siloxane methacrylate, hexafluoroisopropy 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. 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 Keratoconus Contact Lens

The UltraHealth lens 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			8.7 Flat2, 8.4 Flat, 8.1 Med., 7.9 Steep, 7.6 Steep2
Optical Zone Width		6.0 to 6.5 mm	
Center Thickness Range		0.16 – 0.34 mm	
Dioptric Powers		+20.00 to -20.00D	
Front Surface Cylinder Power		Up to 6.00D	
Add Power		+1.00 to +4.00D	

Lens Properties & Characteristics	**RGP Center**	**Soft Skirt**
Refractive Index	1.442 (Nd @ 25ºC)	1.435
Luminous Transmittance (D&C Violet No.2) (380nm to 780nm)*	>90%	97%
Wetting Angle (initial advance angle) (RGP Center)	44º	
Specific Gravity (RGP Center)	1.15	NA
Hardness	76	NA
Oxygen Permeability †	130	84
Water Content	<1%	27%
Overall Water Content	27%	

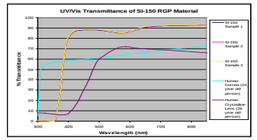
* Ophthalmic optics - Contact lenses - Part 3: Measurement methods, ISO 18369-3:2006
† Ophthalmic optics - Contact lenses – Part 4: Physicochemical properties of contact lens materials, ISO 18369-4:2006

ACTIONS

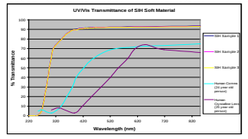
SynergEyes® UltraHealth Contact Lenses act as a refracting medium to focus light rays on the retina.

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:

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



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



INDICATIONS (USES)

UltraHealth SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses for Keratoconus are indicated for the correction of hyperopic, myopic and astigmatic refractive error including presbyopia that manifest irregular corneas or irregular astigmatism, in aphakic and not aphakic, and otherwise non-diseased eyes. The lenses are indicated for the correction of up to +20.00 and –20.00 D in eyes with irregular astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D. The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eyecare professional.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE UltraHealth Hybrid 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 except corneal trauma deemed to benefit from the device. **Or** any active corneal infection (bacterial, fungal or viral).
- Severe insufficiency of tears (dry eyes) or if eyes become red or irritated
- 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 or allergy to any ingredient, e.g., such as mercury or Thimerosal, in a solution that is to be used to care for contact lenses.

WARNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that patients follow the directions of the eyecare practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case. Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:

Soaking and Storing Lenses; Instruction for Use:

Patients should be instructed to use only fresh multi-purpose (contact lens disinfecting) solution each time they soak (store) their lenses. **WARNING***:* Patients should be instructed to not reuse or "top off" old solution left in their lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-Off" is the addition of fresh solution to solution that has been sitting the case.

***a. Rub and Rinse Time* - Instruction for Use:**

- Patients should be instructed to rub and rinse their lenses according to the recommended lens rubbing and rinsing times in the labeling of their multi-purpose solution to adequately disinfect their lenses.

WARNING:

- Patients should be instructed to rub and rinse their lenses for the recommended amount of time to help prevent serious eye infections.
- Patients should be instructed to never use water, saline solution, or rewetting drops to disinfect their lenses. These solutions will not disinfect their lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

***b. Lens Case Care* - Instruction for Use:**

- Patients should be instructed to empty and clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air dry.
- Patients should be instructed to replace their lens case according to the directions given by the eyecare practitioner or the labeling that came with the case.
- Contact lens cases can be a source of bacterial growth.

WARNING:

- Patients should be instructed to not store lenses or rinse the lens case with water or any non-sterile solution.
- Patients should be instructed to only use fresh multi-purpose solution so they do not contaminate their lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

***c. Water Activity* - Instruction for Use:**

- Patients should be instructed to not expose their contact lenses to water while wearing them.

WARNING:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Patients should be instructed that if their lenses have been submersed in water when swimming in pools, lakes or oceans, they should discard them and replace them with a new pair. Patients should be instructed to ask the eyecare practitioner (professional) for recommendations about wearing their lenses during any activity involving water.

***d. Discard Date on Multipurpose Solution Bottle* - Instruction for Use:**

- Patients should be instructed to discard any remaining solution after the recommended time period indicated on the bottle of multipurpose solution used for disinfecting and soaking their contact lenses.
- Patients should be instructed that the Discard Date refers to the time they can safely use contact lens care product after the bottle has been opened. It is not the same as the expiration date, which is the last date that the product is still effective before it is opened.

WARNING:

- Patients should be instructed that using their multi-purpose solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- To avoid contamination, patients should be instructed: DO NOT touch the tip of the container to any surface. Replace cap after using.
- To avoid contaminating their solution, patients should be instructed: DO NOT transfer to other bottles or containers.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF A PATIENT EXPERIENCES:

• Eye Discomfort • Excessive Tearing • Vision Changes • Loss of Vision • Eye Redness • Or Other Eye Problem

THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYECARE PRACTITIONER.

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 the eyecare practitioner's directions and all labeling instructions for proper use of their 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 their eyecare practitioner.

PRECAUTIONS

Special Precautions for Eyecare 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 UltraHealth Hybrid Contact Lenses were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare 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 eyecare practitioner.
- Patients should be instructed that contact lenses are medical devices and parameters or lens type should not be changed without consulting an eyecare professional.
- Patients wearing aspheric 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 Hybrid Contact Lenses; either high or low molecular weight fluorescein can be used.
- Before leaving the eyecare 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.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eyecare 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. Always use fresh unexpired lens care solutions.
- Do not change lens care solutions without consulting the eyecare practitioner.
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- 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 UltraHealth Hybrid Contact Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions. Do not use saliva, tap water or anything other than 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 drying may damage the silicone-hydrogel lens skirt. Follow lens care directions in *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 eyecare 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. 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 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 UltraHealth Hybrid Contact Lenses and those prescribed by the eyecare practitioner. The Patient Instruction Booklet is available at SynergEyes.com.
- Never wear lenses with bubbles present, nor beyond the time recommended by the eyecare practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during sporting activities.

- Always handle lenses carefully and avoid dropping them. 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 eyecare practitioner before using any medicine in the eyes.
- Always inform the employer and doctor (health care practitioner) 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
- Dry eyes
- Feeling of something in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes,
- Unusual eye secretions or redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects or
- Sensitivity to light (photophobia)

If the patient notices any of the above, they 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, instruct patients to NOT put the lens back on their eye. The lens should be placed in the storage case and the patient should contact the eyecare practitioner. If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, the patient should be instructed to 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 their eyecare 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 (KC LENSES)

A one month clinical study of the *SynergEyes KC* Hybrid Contact Lens was conducted to assess safety and effectiveness for vision correction in daily wear for patients suffering from keratoconus and associated refractive errors of nearsightedness, farsightedness, and irregular astigmatism. 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 62 subjects were dispensed into the study of which 44 (71%) subjects completed, and 18 (29%) subjects were discontinued. The population demographics were similar to other contact lens studies with a female to male gender ration of 1.48 to 1.0. The average age of the completed participants was 40.7 and the average age of the discontinued participants was 39.4. **Safety:** Four (4) adverse events were reported during the study for 2 completed subjects and 2 discontinued subjects. One subject presented with mechanical abrasion on the apex of the cone in both eyes after several lens dispensing visits, one subject experienced transient changes in intraocular pressures in both eyes at the 1 week follow-up visit, one subject presented with edema and infiltrates in the left eye 61 days after first lens dispensing, and one subject presented with a red left eye with small infiltrates 14 days after first lens dispensing. Eighteen (18) subjects, or 29% of the 62 dispensed subjects, were discontinued. The most common reasons for discontinuation were poor comfort (38.9%), poor outcome with lenses (16.7%), and 'other' (16.7%). "Other" reasons included patients moved, and lens ripping- too time consuming to restart. Additional reasons for discontinuation included poor vision (11.1%), non-compliance (11.1%), and loss of interest (5.6%). The most common symptoms, problems, and complaints for completed eyes were cited as discomfort/awareness (26%), blurred vision (11.7%) and dryness-scratchiness (12.5%). These rates were higher for discontinued patients (41.6%, 24.7%, and 18.7% respectfully). **Efficacy:** Visual Acuity- Final visual acuity for completed subjects was 20/20 or better (26.3%), 20/25 or better (55.1%), 20/30 (71.4%), and 20/40 or better (83.9%). The visual acuity rates for discontinued subjects were 8.4%, 27.8%, 47.2%, and 52.8% respectfully. Vision correction fluctuated as expected with the instability of the corneal curvature from keratoconus under the contact lens contributing to the change. Five (5) completed eyes and 3 discontinued eyes were reported to have VA decreases of more than 2 lines of Snellen VA when comparing the contact lens VA with the best corrected VA. These findings are expected with this population. **Conclusion:** The *SynergEyes KC* Hybrid Contact Lens for Keratoconus provided satisfactory performance as expected. Discontinuation rates were somewhat higher than normal due to the nature of the subjects enrolled in the study. There were no discontinuations for safety related reasons. Overall, the lens performance demonstrated safe and effective use of the device for Keratoconus.

FITTING

Refer to the Professional Fitting and Information Guide for detailed information on the fitting of the UltraHealth Hybrid Contact Lenses for daily wear. Copies are available from; SynergEyes, Inc., Carlsbad, CA 92008 USA www.synergeyes.com Telephone (USA): +1-760-476- 9410 or FAX: +1-760-476 9340

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 eyecare practitioner regardless of how comfortable the lenses feel. An initial daily wear schedule may be offered at the practitioner's discretion; see example below:

Day 1: wear not to exceed 6 hours total Day 2: 6 hours
Day 3 - Day 5: 8 hours Day 6: Wear as eyecare practitioner allows during waking hours.

The lens only may be worn for daily wear use and for a period of up to six (6) months or as recommended by the eyecare practitioner.
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 replace 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. The lens may be worn for daily wear use for a period of time recommended by the practitioner.

LENS CARE DIRECTIONS

Eyecare 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

- Instruct patients to always wash, rinse, and dry hands before handling contact lenses. Patients should be instructed to always use fresh unexpired lens care solutions.
- Patients should be instructed to 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, patients should be instructed to not use saliva or tap water or anything other than the recommended solutions (ex. non-preserved saline) for lubricating or rewetting and inserting their lenses. Patients should be instructed to not put lenses in their mouth.
- Patients should be instructed that 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. Patients should be instructed to always remove, clean, rinse, enzyme and disinfect their lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection. Patients should be instructed to ensure that tamper proof seal on the solution container is intact prior to initial use. Do not use if tamper proof seal is broken or missing.
- Patients should be instructed that lenses should never be worn while swimming.
- Do not store the lens for prolonged periods at temperatures below 15° C or above 30° C.

Wearing and lens replacement schedules should be determined by the eyecare practitioner. Soft contact lens care products are recommended by SynergEyes for use with the SynergEyes UltraHealth Hybrid Contact Lenses.

NOTE: Patients should be instructed that when using hydrogen peroxide lens care systems, they should **use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** Failure to use the specialized case will result in severe stinging, burning, and injury to their eye. Patients should be instructed to follow the recommendations on the hydrogen peroxide system labeling exclusively and should be instructed that following disinfection with a peroxide system, the lenses should be rinsed with sterile saline.

NOTE**:** SynergEyes® Ultrahealth FC (Flat Cornea) SiH (petrafocon A hem-larafilcon A) Daily Wear Hybrid Contact Lenses for Keratoconus cannot be cleaned and disinfected with the following contact lens solutions: OPTIFREE® PUREMOIST® Solution, Revitalens Ocutec® Multipurpose Disinfection Solution, or Oxysept® Ultracare® Formula Peroxide Disinfection System®.

NOTE: It is the responsibility of the practitioner to ensure that diagnostic lenses are properly cleaned, disinfected, rinsed and stored between uses. Following the solution manufacturer's recommendations for disinfection with any of the above products constitutes the minimum level of care necessary for disinfection as set by the FDA.

1. Clean

While the recommended care products may be approved for a "No Rub" regimen, it is recommended that moderate daily cleaning be conducted for the UltraHealth® Hybrid 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 cleaning or multipurpose solution. Using the ring 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. Disinfection

After cleaning and rinsing the lenses, Disinfection using only a hydrogen peroxide solution that is compatible with both silicone-hydrogel and rigid gas permeable lenses is recommended. Follow the instructions provided with the solution labeling. **Note: UltraHealth Hybrid 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 lenses completely immersed in the saline solution when the lenses are not being worn. If a patient discontinues wearing lenses, but plans to begin wearing them again after a few weeks, they should be instructed to ask the eye care practitioner for a recommendation on how to store the lenses.

5. Care of the Lens Case

Contact lens cases can be a source of bacteria growth. Patients should be instructed that after removing lenses from the lens case, they should 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, it should be refilled with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

6. Lubricating/Rewetting Solutions

The eye care practitioner may recommend a lubricating/rewetting solution for patient use. Patients should be instructed that Lubricating/Rewetting solutions can be used to rewet (lubricate) lenses while they are wearing them to make them more comfortable.

7. Lens Deposits and Use of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by the eyecare 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 the 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. Patients should be instructed to 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, patients should be instructed to 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 the patient should gently push the lens upward with their index finger on the margin of the lower lid. If non-movement of the lens continues after 30 minutes, the patients should be instructed to IMMEDIATELY consult the eyecare practitioner.

9. Care for a Dehydrated Lens

The soft silicone-hydrogel portion of the UltraHealth Hybrid Contact Lenses may become dried out if left exposed to air while the lenses are off the eye. Patients should be instructed to 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 reinsertion.

EMERGENCIES

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

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing UltraHealth Hybrid Contact Lens or experienced with the lens should be reported to:

USA: **SynergEyes, Inc., 2232 Rutherford Road Carlsbad, CA 92008** www.synergeyes.com
Tel.: (760) 476- 9410; FAX: (760)476- 9340

Authorized Representative (European Union): Emergo Europe: Prinsessegracht 20; The Hague, 2514 AP; The Netherlands; Tel.: +31 70 345 8570

HOW SUPPLIED

Each UltraHealth Hybrid Contact Lens is supplied in a sterile glass vial. NOTE: Do not dispense the lens if tamper proof seal is broken or missing. The lens is shipped wet in 0.9% buffered sodium chloride solution. The lenses are shipped as a single lens or in a 2-pack carton package. 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, skirt curve radius, dioptric power, overall diameter, and lot number.

Symbol	Definition
Rx only	**For sale only by or on the order of a physician.**
STERILE R	**Sterilized by irradiation**
	Attention, see instructions for use.
	Use by Date
30°C 15°C	**Upper/Lower limit of temperature**
EC REP	**Authorized Representative**
	Manufacturer
	Do not use if packaged is damaged

Manufactured and Marketed by: ***SynergEyes, Inc., 2232 Rutherford Road, Carlsbad, CA 92008 USA***

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Rx only CE **0086**

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SynergEyes®