



UltraHealth® with Tangible™ Hydra-PEG Daily Wear Hybrid Contact Lenses for Keratoconus

UltraHealth® FC with Tangible™ Hydra-PEG Daily Wear Hybrid Contact Lenses for Post-Surgical Refractive Error and Trauma

CAUTION: SALE OF THIS DEVICE IS RESTRICTED 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 eyecare 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 lenses.*

INTRODUCTION

UltraHealth® and the UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses provide refractive error correction for hyperopia and myopia with and without astigmatism when worn for daily wear. The rigid lens center provides the optics of rigid gas permeable lenses while the hydrogel skirt provides the stability and performance of hydrogel lenses. 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.

PRODUCT DESCRIPTION

UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses are manufactured from SynergEyes rigid gas permeable material (petrafocon A) and SynergEyes silicone hydrogel material (hem-larafilcon A). The lenses are designed to have four zones on the anterior and posterior surfaces:

- | | |
|---|---|
| Rigid Gas Permeable Material (petrafocon A) | <ol style="list-style-type: none"> The central aspherical or spherical optic zone. A secondary curve beginning in the rigid center, crossing into the soft material |
| Silicone Hydrogel Material (hem-larafilcon A) | <ol style="list-style-type: none"> A third curve zone entirely within the soft zone The peripheral anterior edge taper and posterior bevel |

UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses for hyperopia and myopia with and without astigmatism are for daily wear. The central rigid portion of the (petrafocon A hem-larafilcon A) contact lenses are manufactured from a 130Dk rigid gas permeable material (petrafocon A) and the peripheral soft skirt is manufactured from a 33% water silicone hydrogel material (larafilcon A). The central rigid material is a thermoset fluorosilicone acrylate copolymer derived primarily from aromatic siloxane methacrylate, aliphatic siloxane methacrylate, hexafluoroisopropyl methacrylate, hydrophilic methacrylate, cross linkers and UV blocker with a water content of 0.5%. The peripheral skirt material is a silicone hydrogel which is composed of aliphatic siloxane methacrylate, hexafluoro isopropyl methacrylate N, N-dimethylacrylamide and cross linker with a water content of 33.2% ± 1.5%. The overall water content for the hybrid lens is 27.99% ± 1.81%. The lenses are available as lathe cut contact lenses with a violet tint in the rigid central material. The violet material contains D & C No. 2. The silicone hydrogel skirt is clear.

UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses are treated to incorporate Hydra-PEG Technology (HPT)—which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with HPT, the underlying material (petrafocon A hem-larafilcon A) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30nm in thickness. Results of coating durability studies demonstrate improved wettability (reduction of dynamic advancing contact angle vs. untreated lenses) for the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses after 6 months of handling.

The following table depicts the enhanced contact angle of the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG hybrid contact lenses versus the predicate device:

Wettability -- captive bubble contact angle (degrees) (advancing contact angle)*		
Lens	Average	Stdev
UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses (New Device)	21.75°	2.2
UltraHealth® and UltraHealth® FC daily wear hybrid contact lenses(Uncoated) (Predicate Device)	33.50°	9.5

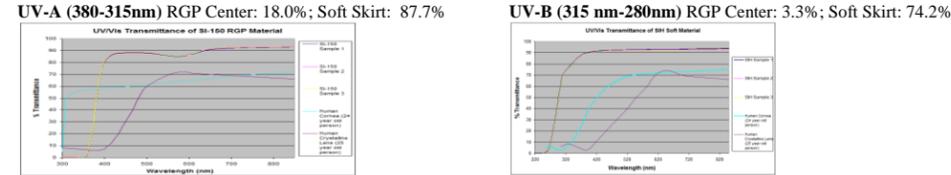
Hydra-PEG coated lenses demonstrate a 35% improvement in wettability vs. uncoated lenses (n = 20). Statistically significant difference for mean contact angle with respect to lens, where the coated lenses had a lower average contact angle than the un-coated lenses (ANOVA, p=0.000)

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 Diameter		6.0 to 6.5 mm	
Center Thickness Range		0.16 to 0.34mm	
Dioptric Powers		+20.00 to -20.00D	
Front Surface Cylinder Power		Up to 6.00D	
Add Power		+1.00 to +4.00	
Lens Properties/Characteristics	RGP Center	Soft Skirt	
Refractive Index	1.442 (Nd @ 25°C)	1.435	
Luminous Transmittance (D&C Violet No. 2) (380nm to 780nm) *	>90%	97%	
Wetting Angle (initial advance angle) (RGP Center)	44°		
Specific Gravity (RGP Center)	1.15	NA	
Hardness	79	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

UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear 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:



Ultra-Violet Transmittance Properties	UVB Transmittance (280-315nm)	UVA Transmittance (315-380nm)	Luminous Transmittance (380-700nm)
Soft Skirt SIH Material	74.2% (±0.9%)	87.7% (±0.4%)	96.7% (±0.6%)
RGP Center (SI-150) + 0.5%UV Blocker	3.3% (±0.1%)	18% (±0.2%)	86.7% (±1.2%)

CAUTION

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the 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 must 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.

INTENDED USE

For daily wear to correct vision conditions in aphakic and non-aphakic, non-diseased eyes and correction of refractive error in eyes.

INDICATIONS (USES)

UltraHealth with Tangible™ Hydra-PEG daily wear 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 –20.00D in eyes with irregular astigmatism up to 6.00D. For presbyopia, add powers between +1.00 and +4.00D.

UltraHealth FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses are indicated for use in the correction of eyes with refractive errors resulting from corneal surgery or trauma including hyperopia and myopia, astigmatism and irregular astigmatism in aphakic and not aphakic, non-diseased eyes with or without presbyopia. The lenses are indicated for the correction of up to +20.00 and –20.00 D in eyes with astigmatism or irregular astigmatism resulting from corneal surgery or trauma up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00 D.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. 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

DO NOT USE the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality, other than conditions such as keratoconus, pellucid marginal degeneration, or post-refractive (e.g., LASIK) surgery, that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.

Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses.

- Any active corneal infection (bacterial, fungi, or viral)
- If eyes become red or irritated.
- Patients 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 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.
- 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 submerged 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.

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.

Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye-care practitioner for more information.

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

All contact lens wearers must see their eyecare practitioner as directed.

PRECAUTIONS

Special Precautions for Eyecare Practitioners:

Due to the small number of patients enrolled in clinical investigation of lens, all refractive powers, design configurations, or lens parameters available in the lens material 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 must 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 who wear aspheric contact lenses to correct presbyopia 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

Fluorescein, a yellow dye, should not be used while the lens is on the eye. The lens will absorb this dye and become discolored. Whenever Fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in eye use. Wait at least one hour before replacing the lens. Too early replacement may allow the lens to absorb residual Fluorescein irreversibly.

Before leaving the eyecare practitioner’s office, the patient should be able to promptly remove lens or should have someone else available who can remove the lens for him or her.

Eyecare practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.

The patient should be instructed to always discard lenses after the recommended wearing schedule for a period of up to six (6) months or as recommended by the eyecare practitioner.

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Contact lenses are medical devices and parameters or lens type should not be changed without consulting an eyecare professional.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions that are fresh and sterile.
- Chemical disinfection solutions should not be used with heat.
- Always use FRESH, STERILE UNEXPIRED lens care solutions.
- Do not change lens care solutions without consulting the eyecare practitioner.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solution for lubricating or rewetting lens.
- Always keep the lens completely immersed in the recommended storage solution when the lens is not being worn (stored). Prolonged periods of drying will damage the lens. Follow the lens care directions for (Care for a Dried Out Dehydrated Dry Lens) if the lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on (care for sticking non-moving 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 lens. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lens. It is best to put on lens before putting on makeup. Water-base cosmetics are less likely to damage lens than oil-base.
- Do not touch contact lens with the fingers or hands if the hands are not free of foreign materials, as microscope scratches of the lens may occur, causing distorted vision and/or injury to the eye.

Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the patient instructions for the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses and those prescribed by the eyecare practitioner. The Patient Instruction Booklet is available at SynergEyes.com.

- Never wear lens beyond the period recommended by the eyecare practitioner.
- Water Activity: do not expose your contact lenses to water while you are wearing them.
- If aerosol products such as hair spray are used while wearing lens, exercise caution and keep eyes closed until the spray has settled.
- Always handle lens carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lens.
- Ask the eyecare practitioner about wearing lens during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lens from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always discard lenses worn on a frequent replacement schedule after the recommended wearing schedule prescribed by the eyecare practitioner.
- Always contact the eyecare practitioner before using any medicine or medications 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 lens.
- Contact lenses should never be shared between users. Sharing contact lenses with someone else increases the risks for serious eye conditions.
- 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

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
- Severe insufficiency of lacrimal secretion (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
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)

During use for the management of irregular corneal conditions, an adverse effect may be due to the original condition or may be due to the effects of wearing a contact lens. There is a possibility that the existing condition might become worse when a lens is used on an eye with an irregular corneal condition. The patient should be instructed to avoid serious eye damage by contacting the eyecare professional IMMEDIATELY if there is an increase in symptoms while wearing the lens.

If the patient notices any of the above, he or she should be instructed to IMMEDIATELY REMOVE the LENS. If discomfort or problems stop, then look closely at the lens. If the lens is in anyway damaged, DO NOT PUT THE LENS BACK ON THE EYE. Place the lens in the storage case and contact the eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses then reinsert them. After reinsertion, if the problem continues, the patient should IMMEDIATELY REMOVE THE LENS AND CONSULT THE EYECARE PRACTITIONER.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to KEEP LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION of the problem and prompt treatment to avoid serious eye damage.

FITTING

Refer to the Professional Fitting and Information Guide for detailed information on the fitting of the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses. Copies are available from:

SynergEyes, Inc., 2232 Rutherford Road, Carlsbad, CA 92008 (USA); www.synergieyes.com
Telephone: (USA) +1-760-476-9410

RECOMMENDED 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, as instructed by the practitioner, until the next scheduled follow-up visit.

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE ULTRAHEALTH® AND ULTRAHEALTH® FC WITH TANGIBLE™ HYDRA-PEG DAILY WEAR HYBRID CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP.

For the management of irregular corneal conditions, close supervision by the eyecare professional is necessary. The eyecare professional should determine the appropriate wearing time and provide specific instructions to the patient regarding lens care, insertion and removal.

WEARING SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER.

Soft contact lens care products are recommended by SynergEyes for use with the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear 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: UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses cannot be cleaned and disinfected using the following contact lens solutions: OPTIFREE® PUREMOIST® Solution, OPTIFREE® Express® Solution, Revitalens Ocutec® Multi-purpose Disinfecting Solution, or Oxsept® Ultracare® Formula Peroxide Disinfecting 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. Soft contact lens care products are recommended by SynergEyes for use with the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses.

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, and disinfect their lenses according to the schedule prescribed by the eyecare practitioner.
- 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.

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® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear 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 multipurpose 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 multipurpose 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 disinfect them by using the multipurpose solution. Follow the instructions provided with the multipurpose solution labeling. Note: UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear 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 multipurpose 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 eyecare practitioner for a recommendation on how to store the lenses.

5. Care of Your Lens Case:

Contact lens cases can be a source of bacteria growth. Patients should be instructed that after removing the 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, 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 eyecare practitioner may recommend lubricating/rewetting solutions for patient use. Patients should be instructed that Lubricating/Rewetting solutions can be used while they are wearing them to make them more comfortable.

7. Lens Deposits and Use of Enzymatic Cleaning Procedure:

Enzyme/Protein Cleaners are NOT recommended for use with the UltraHealth® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses.

8. Care for a Sticking (nonmoving) Lens:

If the lens sticks (stops moving) or cannot be removed, patients should be instructed to apply 5 drops of the recommended saline 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® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear 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 multipurpose 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.

10. Chemical (NOT HEAT) Lens Disinfection:

1. Wash and rinse hands thoroughly BEFORE HANDLING LENS.
2. After removal of lens, CLEAN the lens by applying three drops of cleaner to each surface. Rub and rinse the lenses for 15-20 seconds or more and then repeat with the second side for a total of 2 times 30 seconds or more. Follow the complete recommended lens rubbing and rinsing times in the labeling to adequately disinfect the lenses and reduce the risk of contact lens infection.
3. AFTER CLEANING, thoroughly rinse both surfaces of the lens with a steady stream of fresh, sterile rinsing solution for approximately 10 seconds.
4. Fill contact lens carrying case with the recommended disinfection and storage solution and place lens in the proper cells and soak as recommend in solution labeling.

Note: DO NOT HEAT THE DISINFECTION SOLUTION AND LENS.

Caution: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh, sterile rinsing solution prior to placement on the eye should reduce the potential for irritation.

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® and UltraHealth® FC with Tangible™ Hydra-PEG daily wear hybrid contact lenses or experienced with the lens should be reported to:

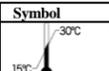
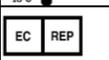
USA: **SynergEyes, Inc., 2232 Rutherford Road Carlsbad, CA 92008** www.synergieyes.com;
Tel.: (760) 476- 9410; FAX: (760)476- 9340

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

HOW SUPPLIED

Each lens is supplied sterile in a sealed glass vial containing buffered normal saline solution. NOTE: Do not dispense the lens if tamper proof seal is broken or missing. The lenses are shipped as a single lens or in a 2-pack carton package. The vial label is marked with the base curve radius, skirt curve radius, dioptric power, overall diameter, and lot number and expiration date. In addition, the vial label will show icons for Rx Only and Sterile. The packing slip or invoice is marked with the base curve radius, skirt curve radius, dioptric power, overall diameter, and lot number.

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

Symbol	Definition
	Upper/Lower limit of temperature
	Authorized Representative
	Manufacturer
	Do not use if packaged is damaged

 Manufactured and Marketed by: *SynergEyes, Inc., 2232 Rutherford Road, Carlsbad, CA 92008 USA*
P/N 70161 Rev. F ECR 1138 August 1, 2018



Australian Sponsor: Emergo Asia Pacific Pty Ltd; ACN 108 597 of Level 20; Tower II Darling Park; 201 Sussex Street; Sydney, NSW 2000, Australia;
Tel: +61 (0) 29006.1662 or Fax: +61 (0) 29006.