Duette, Duette Progressive CN, Duette Progressive CD, Duette Multifocal, UltraHealth, UltraHealth FC

SiH (petrafocon A hem-larafilcon A) with Tangible™ Hydra-PEG HYBRID CONTACT LENSES FOR DAILY WEAR

Rx only ***CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYECARE 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 lens.

Duette, Duette Progressive CN, Duette Progressive CD, Duette Multifocal with Tangible™ Hydra-PEG

DESCRIPTION:

SynergEyes Duette, Duette Progressive CN, Duette Progressive CD, and Duette Multifocal SiH (petrafocon A hem-larafilcon A) with Tangible™ Hydra-PEG Hybrid Contact Lenses for hyperopia and myopia with and without astigmatism, and presbyopia are for daily wear.

Duette SiH Lens Parameters Available:	RGP Center	Soft Skirt	Overall Lens
Diameter (Approximate)	-	-	14.5 mm
Base Curve Radius	6.9 to 8.9 mm	-	-
Skirt Curve	-	7.9 to 8.7 mm	-
Posterior Optical Zone Diameter	7.0 mm	-	-
Center Thickness Range	0.12 to 0.34 mm	-	-
Dioptric Power	-20.00 to +20.00 D	-	-
Add Power – Duette Multifocal	+1.00 to +4.00 D	-	-
Add Power – Duette Progressive Center Near	+1.00 to +4.00 D	-	-
Add Power – Duette Progressive Center Near	+0.50 to +6.00 D	-	-
Lens Physical/Optical Properties			
Refractive Index	1.442 Nd at 25°C	-	-
Luminous Transmittance (D&C Violet No.2) (380 to 780 nm)*	>90%	-	-
Wetting Angle (initial advance angle)	≤44°	-	-
Specific Gravity	1.15	-	-
Oxygen Permeability †	130	84	-
Water Content	<1%	27%	-

* Ophthalmic Optics - Contact Lenses - Part 3: Measurement Methods, ISO 18369-3,
† Ophthalmic Optics - Contact Lenses - Part 4: Physicochemical Properties of Contact Lens Materials, ISO 18369-4

INDICATIONS FOR USE:

Duette SiH (petrafocon A hem-larafilcon-A) with Tangible™ Hydra-PEG Hybrid Contact Lenses are indicated for use in the correction of hyperopic, myopic and astigmatic refractive error including presbyopia, in aphakic and not aphakic, non-diseased eyes. The lenses are indicated for the correction of up to -20.00 and +20.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers for Duette Multifocal and Duette Progressive Center Near lenses are between +1.00 D and +4.00 D. For presbyopia, add powers for Duette Progressive Center Distance lenses are between +0.50 D and +6.00 D. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using only a chemical (not heat) disinfecting system compatible with both silicone-hydrogel and rigid gas permeable lenses.

UltraHealth and UltraHealth FC with Tangible™ Hydra-PEG

DESCRIPTION:

SynergEyes® UltraHealth® SiH (petrafocon A larafilcon A) with Tangible™ Hydra-PEG Hybrid Contact Lenses for Keratoconus provide refractive error correction for keratoconus, and are intended for daily wear. The UltraHealth with Tangible™ Hydra-PEG 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.

SynergEyes® UltraHealth® FC (Flat Cornea) SiH (petrafocon A hem-larafilcon A) with Tangible™ Hydra-PEG Hybrid Contact Lenses for Post-Surgical Refractive Error and Trauma provide refractive error correction for post-surgical or traumatic corneal conditions, and are intended for daily wear. 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. Post lens tear exchange is facilitated by a peristaltic pumping action upon blinking and assisted by the minimal edge clearance provided by the peripheral bevel. The maximum central thickness of minus power lenses and the maximum junction thickness of plus power lenses is 0.30 mm. The center thickness of minus power lenses and the anterior optic zone junction thickness of plus power lenses reduces as the lens power increases to hold a constant rigid – soft junction thickness, soft skirt thickness and lens edge thickness. The UltraHealth FC with Tangible™ Hydra-PEG edge is pre-specified and equivalent in all lenses regardless of their other parameters. The anterior central curve is selected to provide any necessary optical power to correct spherical and cylindrical refractive error not corrected by the optical and mechanical 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 astigmatism uncorrected by the lenses. The amount of residual astigmatism may be estimated by comparison of the corneal and refractive astigmatism. Eyes with near equal corneal and refractive astigmatism are not expected to demonstrate residual astigmatism. Eyes with a disparity between corneal and refractive astigmatism > 0.75 D may demonstrate residual astigmatism and may require a non-rotating lens with a toric anterior surface.

UltraHealth and UltraHealth FC Lens Parameters Available:	RGP Center	Soft Skirt	Overall Lens
Diameter (Approximate)	-	-	14.5 mm
Vault	-	-	0.05 to 0.75 mm
Skirt Curve	-	8.7 Flat2, 8.4 Flat, 8.1 Med., 7.9 Steep, 7.6 Steep2	-
Posterior Optical Zone Diameter	6.0 to 6.5 mm	-	-
Center Thickness Range	0.16 to 0.34 mm	-	-
Dioptric Power	-20.00 to +20.00 D	-	-
Add Power - Multifocal	+1.00 to +4.00 D	-	-
Lens Physical/Optical Properties			
Refractive Index	1.442 (Nd @ 25°C)	-	-
Luminous Transmittance (D&C Violet No.2) (380 to 780 nm)*	>90%	-	-
Wetting Angle (initial advance angle)	≤44°	-	-
Specific Gravity	1.15	-	-
Oxygen Permeability †	130	84	-
Water Content	<1%	27%	-

INDICATIONS FOR USE:

UltraHealth SiH (petrafocon A hem-larafilcon A) with Tangible™ Hydra-PEG 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. 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.

UltraHealth FC (Flat Cornea) SiH (petrafocon A hem-larafilcon A) with Tangible™ Hydra-PEG 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.

All SiH with Tangible™ Hydra-PEG Hybrid Contact Lens Models

DESCRIPTION:

All SynergEyes SiH with Tangible™ Hydra-PEG Hybrid Contact Lenses are manufactured from rigid gas permeable material (petrafocon A) and a poly-silicone hydrogel material (hem-larafilcon A). The lens center provides the optics of rigid gas permeable lenses while the silicone-hydrogel skirt provides stability and performance of silicone hydrogel lenses. Greater attention must be directed toward fitting the lens than with soft 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. 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, hexafluoroisopropyl 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.

RGP Material:	The central aspherical or spherical zone
Silicone Hydrogel 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

The SiH with Tangible™ Hydra-PEG 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 30 nm in thickness. Results of coating durability studies demonstrate improved wettability (reduction of dynamic advancing contact angle vs. untreated lenses) for the SiH with Tangible™ Hydra-PEG hybrid contact lenses after 6 months of handling. The following table depicts the enhanced contact angle of the SiH with Tangible™ Hydra-PEG hybrid contact lenses versus the predicate device:

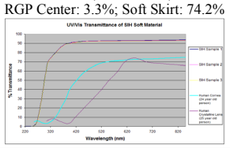
Wettability -- captive bubble contact angle (degrees) (advancing contact angle)*		
Lens	**Average**	**Standard Deviation**
SiH with Tangible™ Hydra-PEG	21.75°	2.2
SiH (Uncoated)	33.50°	9.5

* 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).

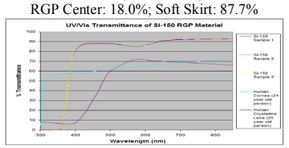
ACTIONS:

The SiH with Tangible™ Hydra-PEG Hybrid Contact Lenses, when placed on the cornea, 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 (0.12 mm) at power range from -20.00 D to +20.00 D (thinnest lenses) are as follows:

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



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



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

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE SiH with Tangible™ Hydra-PEG Hybrid Contact Lenses when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Severe insufficiency of lacrimal secretion (dry eyes).
- If eyes become red or irritated.
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- 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 which is to be used to care for SiH with Tangible™ Hydra-PEG Hybrid Contact Lenses.
- Any active corneal infection (bacterial, fungal, or viral).
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.
- **Duette Models:** Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- **UltraHealth**: Any eye disease (excluding Keratoconus), injury, or abnormality that affects the cornea, conjunctiva or eyelids except corneal trauma deemed to benefit from the device.
- **UltraHealth FC**: Any eye disease 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.

WARNINGS:

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION. THE PATIENT SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYECARE PRACTITIONER IF THEY EXPERIENCE:

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

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 direction 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, loss of vision, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact their eyecare practitioner.
- 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.
- All contact lens wearers must see their eyecare practitioner as directed.

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 approved, fresh 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.
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 disinfecting 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.
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. It is recommended that cleaning is followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with a fresh, clean tissue. After use, never air-dry or recap the lens case lids without performing proper 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.
Warning	• Contact lens cases can be a source of bacterial growth. • 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 disinfecting 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.
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 for recommendations about wearing their lenses during any activity involving water.
Discard Date on Contact Lens Disinfecting Solution Bottle:	
Instruction for Use	• Patients should be instructed to discard any remaining solution after the recommended time period indicated on the bottle of disinfecting 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 disinfecting 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.

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 SiH with Tangible™ Hydra-PEG Hybrid Contact 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 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 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.
- Aphakic patients should not be fitted with SiH with Tangible™ Hydra-PEG Hybrid Contact Lenses until the determination is made that the eye has healed completely.

- When using fluorescein in the fitting evaluation of Hybrid Contact Lenses; either high or standard molecular weight fluorescein can be used. The soft skirt of the lens may 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. Lens discoloration may be reversed following the ISO guidelines for hygienic management of multipatient use trial lenses; if dye is still present, increase the hydrogen peroxide soak time.
- 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 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:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions. Chemical disinfection solutions should not be used with heat.
- Always use fresh, 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.
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- Use only a chemical (NOT HEAT) lens care system. Use of a heat (thermal) care system can warp the center of the SiH with Tangible™ Hydra-PEG 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 periods of drying may damage the silicone-hydrogel lens skirt. If the lens skirt becomes dried out, follow the Care for a *Dehydrated Lens* section of this instruction sheet.
- If the lens sticks (stops moving) on the eye, follow the *Care for a Sticking Lens* section of this instruction sheet. 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. 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 hands are not free of foreign materials; 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 the SiH with Tangible™ Hydra-PEG Hybrid Contact Lenses and those prescribed by the eyecare practitioner. The Patient Instruction Booklet is available at SynergEyes.com.
- Never wear lenses beyond the period 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.
- 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.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Always inform the employer about being a contact lens wearer; some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- 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 in the eyes.
- Contact lenses are medical devices and parameters or lens type should not be changed without consulting an eyecare practitioner.
- Contact lenses should never be shared between users. Sharing contact lenses with someone else increases the risks for serious eye conditions.
- Never wear lenses with bubbles present.
- 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
- 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 THE EYE. Place the lens in the storage case and 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, then thoroughly clean, rinse, and disinfect the lens; then reinsert it.
- 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 THE LENS OFF THE EYE AND SEEK IMMEDIATE PROFESSIONAL IDENTIFICATION OF THE PROBLEM AND PROMPT TREATMENT TO AVOID SERIOUS EYE DAMAGE.

UltraHealth and UltraHealth FC: 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.

FITTING:

Refer to the Professional Fitting Guide for detailed information on the fitting of the SiH with Tangible™ Hydra-PEG Hybrid Contact Lens for daily wear. Copies are available from: SynergEyes, Inc. www.synergeyes.com, Telephone: (USA) +1-760-476-9410

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. Studies have not been completed to show that the SiH with Tangible Hydra-PEG Hybrid Contact Lens is safe to wear during sleep.

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 on the eye. 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.

WEARING AND LENS REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE 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:

- 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.
- Do not use saliva, tap water, or anything other than the recommended solutions (e.g. non-preserved saline) for lubricating or rewetting lenses. Do not put lenses in the 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, and disinfect lenses according to the schedule prescribed by the eyecare practitioner.
- Ensure that the tamper-proof seal on the solution container is intact prior to initial use; do not use if tamper-proof seal is broken or missing.
- Lenses should never be worn while swimming.
- Do not store the lens for prolonged periods at temperatures below 15° C or above 30° C.

NOTE:

Soft contact lens care products are recommended by SynergEyes for use with the SynergEyes SiH with Tangible™ Hydra-PEG **Hybrid Contact Lenses.** SynergEyes® SiH (petrafocon A hem-larafilcon A) with Tangible™ Hydra-PEG Hybrid Contact Lenses cannot be cleaned and disinfected using the following contact lens solutions: OPTIFREE® PUREMOIST® Solution, OPTIFREE® Express® Solution, Revitalens Ocutec® Multipurpose Disinfecting Solution, or Oxysept® Ultracare® Formula Peroxide Disinfecting System®.

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 constitutes the minimum level of care necessary for disinfection as set by the FDA.

UltraHealth and UltraHealth FC: 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.

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 SiH with Tangible™ Hydra-PEG 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 contact lens cleaning or disinfecting solution. Using the ring finger of the other hand, apply slight pressure in a swirling motion for the time recommended by the disinfecting 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 disinfecting solution to remove mucus and film from the lens surface; place the lens into the correct chamber of the lens storage case. Repeat this rinsing procedure for the second lens. Avoid rinsing the lens over the sink and avoiding the use of tap water as tap water contains many impurities that can contaminate or damage the lens and lead to eye infection or injury.

3. Disinfect:

After cleaning and rinsing the lenses, disinfect them by using the disinfecting solution. Follow the instructions provided with the disinfecting solution labeling. **NOTE: SynergEyes SiH with Tangible™ Hydra-PEG Hybrid Contact Lenses cannot be heat (thermally) disinfected.** When using hydrogen peroxide lens care systems, instruct the patient to 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 the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline prior to use. 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.

4. Store:

To store lenses after disinfection, leave them in the closed/unopened case until ready to wear. Always keep lenses completely immersed in the disinfecting solution when the lenses are not being worn. If the patient discontinues wearing lenses, but plans to begin wearing them again after a few weeks, they should ask the eyecare practitioner for storage recommendations.

5. Care of the Lens Case:

Contact lens cases can be a source of bacteria growth. 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, refill it with fresh storage 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 which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable.

7. Lens Deposits and Use of Enzymatic Cleaning Procedure:

Enzyme/Protein cleaners are NOT recommended for use with the SiH with Tangible Hydra-PEG Hybrid Contact Lenses.

8. Care for a Sticking Lens:

If the lens sticks (stops moving) or cannot be removed, 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 the index finger on the margin of the lower lid. If non-movement of the lens continues after 30 minutes, the patient should IMMEDIATELY consult the eyecare practitioner.

9. Care for a Dehydrated Lens:

The soft silicone hydrogel portion of the SiH with Tangible™ Hydra-PEG Hybrid Contact Lens may become dried out if left exposed to air while the lenses are off the eye. Patients should 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. If, after soaking, the lens does not become soft or if the surface remains dry, instruct the patient to NOT USE THE LENS UNLESS IT HAS BEEN EXAMINED BY THE EYECARE PRACTITIONER.

EMERGENCIES:

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

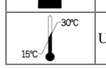
REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing SiH with Tangible™ Hydra-PEG Hybrid Contact Lens or experienced with the lens should be reported to:

	SynergEyes, Inc., 2232 Rutherford Road Carlsbad, CA 92008 www.synergeyes.com Phone: (760) 476- 9410; Fax: (760) 476- 9340
Australian Sponsor:	Emergo Australia: Level 20, Tower II, Darling Park, 201 Sussex Street, Sydney, NSW 2000, Australia

HOW SUPPLIED:

Each SiH with Tangible™ Hydra-PEG Hybrid Contact Lens is supplied sterile, in a sealed glass vial containing 0.9% buffered sodium chloride solution. NOTE: Do not dispense the lens if the tamper proof seal is broken or missing. The lenses are shipped as either a single lens or in a 2-pack carton package. The vial label is marked with the base curve radius/vault, skirt curve, diopter power, diameter, lot number, and expiration date. In addition, the vial label will show Rx Only and Sterile symbols. The packing slip or invoice is marked with the base curve radius, skirt curve, diopter power, diameter, and lot number.

Symbol	Definition
	Manufacturer
	Sterilized by irradiation
	Consult instructions for use
	Caution, consult instructions for use for important cautionary information
	Use-by date
	Upper/Lower limit of temperature

Symbol	Definition
	Caution: Federal law restricts this device to sale by or on the order of a licensed eyecare practitioner.
	Do not use if packaged is damaged
	Lot number
	Catalogue number
Parameter Abbreviations	
Diameter (DIA), Base Curve Radius (BC), Vault (VLT), Skirt Curve Radius (SC), Diopter Power (PWR), Add Power – Multifocal Only (ADD), Zone – Multifocal Only (ZN)	

SUMMARY OF CLINICAL STUDIES:

Duette Models: A three month clinical study of the Silicone Hydrogel Hybrid 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 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 (2) 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. Conclusion: The Silicone Hydrogel Hybrid Contact Lens (hybrid contact lens with a silicone hydrogel skirt) provided satisfactory performance as expected. Discontinuation rates were somewhat higher than normal due to the reasons cited above. Discontinuations for safety related reasons were evaluated in the context of the events and all fully recovered. Overall, the lens performance demonstrated safe and effective use of the device for its intended use.

UltraHealth: 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.

UltraHealth FC: A three month clinical study of the SynergEyes® PS Hybrid Contact Lens for Post-Surgical Refractive Error and Trauma was conducted to assess safety and effectiveness for vision correction in daily wear for patients suffering from post-surgical refractive error including nearsightedness, farsightedness, astigmatism and irregular astigmatism, or trauma to the eye. 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 76 subjects were dispensed into the study of which 44 (80 eyes) [57.9%] completed the study and 32 subjects (58 eyes) [42.1%] were discontinued from the study. An additional 8 subjects were not dispensed lenses. The population demographics were similar to other contact lens studies with a female to male gender ration of 1.3 to 1.0. The average age of the completed and discontinued subjects was 49 and 43.5 respectfully. Safety: Eight (8) adverse events were reported during the study for 4 completed subjects and 3 discontinued subjects. The adverse events included 1 painful light sensitivity (photophobia); 1 loose interrupted suture and infiltrate; 1 abrasion of the cornea upon lens removal; 1 small superficial abrasion; 1 subject (2 eyes) with swelling of the corneas due to inadequate rinsing of hydrogen peroxide disinfection solution from lenses; 1 allergic conjunctivitis; and 1 keratitis iritis. Thirty-two (32) subjects (58 eyes) [42.1%] were discontinued from the study. An additional 8 subjects were never dispensed lenses. The most common reasons for discontinuation were poor outcome with lenses (32.5%), poor comfort (27.5%), poor vision (12.5%), loss of interest (10.0%), non-compliance (10.0%), and handling difficulty (2.5%). Symptoms, Problems, and Complaints: For the completed eyes, no symptoms were reported at 46.2% of the dispensing visit or follow-up visit examinations and for discontinued eyes no symptoms were reported at 28.8% of the dispensing visit or follow-up visit examinations. Symptoms decreased over time for completed eyes but not for discontinued eyes. The most common symptoms reported were discomfort and awareness (28.4% completed, 45.8% discontinued), dryness and scratchiness (23.4%, 22.1%), itchiness and burning (9.3%, 8.9%), and variable vision (8.2%, 13.3%). Efficacy: Visual Acuity- Final visual acuity for completed subjects was 20/20 or better (20.0%), 20/25 or better (45.0%), 20/30 (68.8%), and 20/40 or better (81.3%). The visual acuity rates for discontinued subjects were 8.6%, 39.7%, 53.4%, and 70.7% respectfully. Vision correction fluctuated as expected with the instability of the corneal curvature from post-surgical conditions and trauma under the contact lens contributing to the change. Three (3) completed eyes and 8 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. Wearing Time: Over the study period the average daily wearing time reported by completed patients was 10.6 hours per day. Conclusion: The SynergEyes® PS Hybrid Contact Lens for Post-Surgical refractive error and cases involving trauma provided satisfactory performance as expected. The higher than estimated discontinuation rate was anticipated due to the nature of the subject population with the inclusion of subjects who might otherwise have less successful outcomes with other lens types. Overall, the lens performance demonstrated safe and effective use of the device for its intended use.