



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



CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PRACTITIONER.

Important: Please read carefully and keep this information for future use. This package insert is intended for the eye care practitioner but should be made available to patients upon request. The eye care practitioner should provide the patient with patient instructions that pertain to the patient’s prescribed lens.

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 (for EP add 0.09 mm)	0.16 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 Distance	+0.50 to +6.00 D	-	-
Lens Physical/Optical Properties			
Refractive Index	1.442 Nd @ 25°C	-	-
Spectral 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 Daily Wear 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 daily wear 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. Eye care 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-ear 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	-

UltraHealth and UltraHealth FC Lens Parameters Available:	RGP Center	Soft Skirt	Overall Lens
Posterior Optical Zone Diameter	6.0 to 6.5 mm	-	-
Center Thickness Range (for EP add 0.09 mm)	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)	-	-
Spectral 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 Daily Wear 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 daily wear for the correction of up to +20.00 and -20.00 D in eyes with irregular astigmatism up to 6.00 D. Eye care 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 FC (Flat Cornea) SiH (petrafocon A hem-larafilcon A) with Tangible Hydra-PEG Hybrid Daily Wear 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 daily wear 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. Eye care 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.

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 The intermediate aspherical or spherical zone
Silicone Hydrogel Material:	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:

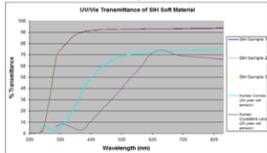
Wettability – captive bubble contact angle (degrees) (advancing contact angle) *	Average	Standard Deviation
SiH with Tangible Hydra-PEG	21.75°	2.2
SiH (Uncoated)	33.50°	9.5

* 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).

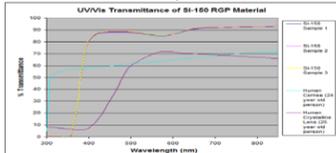
ACTINGS:

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	Spectral 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 EYE CARE 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 eye care 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 eye care 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 eye care 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 eye care practitioner or the labeling that came with the case.
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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.
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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 eye care 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 Eye Care Practitioners:

- Clinical studies demonstrated that contact lenses manufactured from the SynergEyes material are safe and effective for daily wear. Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the 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 eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear aspheric contact lenses to correct 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.

