SynergEyes® PS (paflufocon D – hem-iberfilcon A) HYBRID CONTACT LENS FOR DAILY WEAR for POST SURGICAL CORNEAL SURGERY CORRECTION OR TRAUMA CAUTION*: 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 lens.*

INTRODUCTION

SynergEyes® PS (paflufocon D-hem-iberfilcon A) contact lenses for Post-Surgical Refractive Error and Trauma provide refractive error correction in daily wear for post-surgical or traumatic corneal conditions. The lenses are manufactured from Paragon HDS® 100 with a poly-hema hydrogel skirt. The 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.

DESCRIPTION

SynergEyes PS Hybrid Contact Lenses for Post-Surgical Refractive Error and Trauma are manufactured from rigid gas permeable material (paflufocon D) and SynergEyes poly-hema material (hem-iberfilcon A). The lenses are designed to have at least four zones on the anterior and posterior surfaces:

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

SynergEyes PS Hybrid Contact Lenses for Post-Surgical Refractive Error and Trauma are for daily wear. The center material is a thermoset fluorosilicone acrylate copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate and methylmethacrylate. The peripheral skirt material is a poly-hema hydrophilic copolymer. The lenses are available as lathe cut contact lenses with a blue tint in the rigid central material. The blue material contains D&C Green No. 6. The poly-hema skirt is clear.

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 SynergEyes® PS Hybrid contact lens 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 of greater than 0.75 D may demonstrate residual astigmatism and may require the non-rotating design with a toric anterior surface.

Lens Parameters Available	**Overall Lens**	**RGP Center**	**Soft Skirt**
Overall Diameter (D)	14.5mm		
Central Base Curve Radius		7.1 – 9.0 mm	
Base Curve Radius-Soft Skirt			8.3 to 8.6 mm
Optical Zone Diameter		6.5 mm	
Center Thickness Range		0.16- 0.34 mm	
Peripheral Bevel (Blend) Radius			11.0 to 12.0 mm
Peripheral Bevel Width			0.35mm
Dioptric Powers		+20.00 to -20.00D	
Front Surface Cylinder Power		Up to 6.00D	
LENS CHARACTERISTICS		**RGP Center**	**Soft Skirt**
Refractive Index		1.442(Nd at 25°C)	
Luminous Transmittance(D&C Green 6) (380nm to 780nm)*		>90%	95%
Wetting Angle (Receding Angle) (RGP Center)		42^0	N/A
Specific Gravity (RGP Center)		1.10	N/A
Hardness (RGP Center)		79	N/A
Oxygen Permeability (RGP Center)†		100	
Oxygen Permeability (Soft Skirt)†			9.3
Water Content (RGP Center)		<1%	
Water Content (Soft Skirt)			27%

* Ophthalmic optics - Contact lenses - Part 3: Measurement methods, ISO 18369-3:2006

† Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials, ISO 18369-4:2006

ACTIONS

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

INDICATIONS (USES)

SynergEyes PS 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. 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. The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion as recommended by the eyecare professional.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE SynergEyes PS Hybrid Contact Lenses for Post Surgical Refractive Error and Trauma when any of the following conditions exist:

- Acute and sub-acute inflammations or infection of the anterior chamber of the eye.
- Any eye disease-excluding keratoconus, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (dry eyes) **or** if eyes become red or irritated
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution that is to be used to care for contact lenses.
- Any active corneal infection (bacterial, fungal or viral).

WARNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow the directions of the eyecare practitioner and all labeling instructions for proper use of contact lenses and lens care products, including the lens case. Patients should be advised of the following instructions for use and warnings pertaining to contact lens wear:

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

a. Rub and Rinse Time
Instruction for Use:
- Patients should be instructed to rub and rinse their lenses according to the recommended lens rubbing and rinsing times in the labeling of their multi-purpose solution to adequately disinfect their lenses.

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

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

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

c. Water Activity
Instruction for Use:
- Patients should be instructed to not expose their contact lenses to water while wearing them.

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

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

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

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; IF A PATIENT EXPERIENCES:
• Eye Discomfort • Excessive Tearing • Vision Changes • Loss of Vision • Eye Redness • Or Other Eye Problem

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

Patients should be advised of the following warnings pertaining to contact lens wear:
- Problems with contact lenses and lens care products could result in serious injury to the eye**.** It is essential that the patient follow the eyecare practitioner's directions and all labeling instructions for proper use of their lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences: eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove the lens and promptly contact their eyecare practitioner.

PRECAUTIONS

Special Precautions for Eyecare Practitioners:
- Clinical studies demonstrated that contact lenses manufactured from the SynergEyes material are safe and effective for daily wear. Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the SynergEyes PS Hybrid Contact Lens were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.
- Patients should be instructed that contact lenses are medical devices and parameters or lens type should not be changed without consulting an eyecare professional.
- Patients who wear aspheric contact lenses to correct far or near vision may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Standard fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The poly-hema skirt of the lens may absorb this dye and become discolored. Whenever standard fluorescein is used in eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use. The fitting evaluation should be performed using large molecule fluorescein.
- Before leaving the eyecare practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.
- Eyecare practitioners should instruct the patient to remove the lenses immediately if the eyes become red or irritated.

Eyecare practitioners should carefully instruct patients about the following care regimen and safety precautions:
- Different solutions cannot always be used together; not all solutions are safe for use with all lenses. Use only recommended solutions. Always use fresh unexpired lens care solutions.
- Do not change lens care solutions without consulting the eyecare practitioner.
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Use only a chemical (NOT HEAT) lens care system. Use of a heat lens care system can warp the center of the SynergEyes PS Hybrid Contact Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or tap water or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged period of drying may damage the poly-hema lens skirt. Follow the lens care directions on *Care for a Dried out Lens* if the lens skirt becomes dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on *Care for a Sticking Lens.* The lens should move freely on the eye for the continued health of the eye. If nonmovement 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 the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Instruction Booklet for the SynergEyes PS Hybrid contact lenses and those prescribed by the eyecare practitioner. The Patient Instruction Booklet is available at SynergEyes.com.
- Never wear lenses with bubbles present, or beyond the time recommended by the eyecare practitioner.
- If aerosol products such as hairspray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always contact the eyecare practitioner before using any medicine in the eyes.

- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

Patients should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye **or** dry eye
- Feeling of something in the eye such as a foreign body or scratched area
- Excessive watering (tearing) of the eyes
- Unusual eye secretions **or** redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)

If the patient notices any of the above, they should be instructed to: **IMMEDIATELY REMOVE THEIR LENSES**.

- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, DO NOT put the lens back on their eye. Place the lens in the storage case and the patient should contact the eyecare practitioner. If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, the patient should be instructed to thoroughly clean, rinse and disinfect the lens; then reapply it.
- After reapplication of the lens, if the problem continues, the patient should IMMEDIATELY remove the contact lens and consult the eyecare practitioner.
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. Keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

SUMMARY OF CLINICAL STUDY

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:** SynergEyes PS Hybrid Contact Lenses 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.

FITTING

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

RECOMMENDED INITIAL WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following is recommended as a guideline. Patients should be cautioned to limit the wearing schedule to the level recommended by the eyecare practitioner regardless of how comfortable the lenses feel. An initial daily wear schedule may be offered at the practitioner's discretion; see example below:

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

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

A well fit lens provides for centration and minimal movement. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. Patients must be cautioned; "when in doubt, take it out". It is important that the new wearer not over wear the lens or endure a lens that has an obvious foreign body sensation. In the event of foreign body sensation, the patient should be instructed to remove the lens, clean and rinse it and replace the lens. If the sensation continues, the lens should not be worn.

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

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

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

NOTE: SynergEyes PS (paflufocon D hem-iberfilcon A) Hybrid Contact Lenses cannot be cleaned and disinfected using the following contact lens solutions: OPTIFREE® PUREMOIST® Solution, Revitalens Ocutec® Multipurpose Disinfecting Solution, or Biotrue® Multipurpose Solution.

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.

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 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 enzyme and disinfect their lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection. Patients should be instructed to ensure that tamper proof seal on the solution container is intact prior to initial use. Do not use if tamper proof seal is broken or missing.
- Patients should be instructed that lenses should never be worn while swimming.
- Do not store the lens for prolonged periods at temperatures below 15° C or above 30° C.

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 SynergEyes PS 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 index 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: SynergEyes PS 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 the patient discontinues wearing the 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 the 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, they should empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, it should be refilled with fresh disinfecting solution. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the eyecare practitioner.

6. Lubricating/Rewetting Solutions

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

7. Lens Deposits and Use of Enzymatic Cleaning Procedure

Enzyme cleaning may be recommended by the eyecare practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation. Enzyme cleaning does not replace routine cleaning and disinfecting. Patients should be instructed to carefully follow the instructions in the enzymatic cleaning labeling.

8. Care for a Sticking (nonmoving) Lens

If the lens sticks (stops moving) or cannot be removed, patients should apply 5 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. To initiate movement the patient should gently push the lens upward with their index finger on the margin of the lower lid. If non-movement of the lens continues after 30 minutes, the patient should IMMEDIATELY consult the eyecare practitioner.

9. Care for a Dehydrated Lens

The soft poly-hema portion of the SynergEyes PS Hybrid Contact Lens 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.

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 SynergEyes PS Hybrid Contact Lenses or experienced with the lenses should be reported to:

USA:	**SynergEyes, Inc., 2232 Rutherford Road Carlsbad, CA 92008** www.synergeyes.com **Tel.: (760) 476- 9410; FAX: (760)476- 9340**
EC REP	**Authorized Representative (European Union): Emergo Europe: Prinsessegracht 20; The Hague, 2514 AP; The Netherlands; Tel.: +31 70 345 8570**

HOW SUPPLIED

Each Synergeyes Hybrid Contact Lens is supplied in a sterile glass vial. NOTE: Do not dispense the lens if tamper proof seal is broken or missing. The lens is shipped wet in 0.9% buffered sodium chloride solution. The lenses are shipped as a single lens or in a 2-pack carton package. The vial label is marked with the central equivalent base curve radius, skirt curve radius, dioptric power, overall diameter, lot number, and expiration date. In addition, the vial label will show icons for Rx only and Sterile marks. The packing slip or invoice is marked with the central equivalent base curve radius, skirt curve radius, dioptric power, overall diameter, and lot number.

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

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

P/N 70115 Rev. E **May 24, 2017**

Rx only CE **0086**

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) 2.9006.1662 or Fax: +61 (0) 2.9006.

SynergEyes