and not aphakic, non-diseased eyes. The lenses are indicated for the correction of up to +20.00 and –20.00 D in eyes

Important: Please read disinfection (chemical, not heat) prior to reinsertion as recommended by the eyecare professional.

INTRODUCTION
SynergEyes® PS (paflufocon D-hem-iberfilcon A) 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 five features should the patient choose to use them.

RGP
The central apical or spherical zone
HEMA
The peripheral anterior tear and posterior bevel
Material
Polymethacrylate and methylenacrylate

An essential feature of the SynergEyes PS Hybrid Contact Lens System is the use of a toric material. The lens should be toric to ensure that the patient’s astigmatism is corrected to the best extent possible. The toric material is designed to provide an optimum scleral relationship and the power of the lens is modulated to provide the desired refractive outcome.

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 five features should the patient choose to use them.

RGP
The central apical or spherical zone
HEMA
The peripheral anterior tear and posterior bevel
Material
Polymethacrylate and methylenacrylate

Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than non-smokers. Patients should be instructed to not store or reuse or “top off” old solution left in their lens case. Patients should be instructed that contact lenses are medical devices and parameters or lens type should not be changed without consulting an eyecare professional.

PRECAUTIONS
SynergEyes PS Hybrid Contact Lens System is a medical device and parameters or lens type should not be changed without consulting an eyecare professional.

Patient Instruction Booklet for the SynergEyes PS Hybrid contact lenses and those prescribed by the eyecare practitioner. Do not use a commercially available lens care product. Do not open the bottle until the bottle has been opened.

Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. Patients should be instructed to not store their lenses or rinse their lenses in water or any non-sterile solution. Always contact the eyecare practitioner before using any medicine in the eyes.

Contradictions (Reasons Not to Use)
DO NOT USE SynergEyes PS Hybrid Contact Lenses for Post Surgical Refractive Error and Trauma when:

• Acute and sub-acute infections or inflammation of the anterior chamber of the eye.
• Severe dryness or irritation of the cornea, conjunctiva or eyelids.
• Severe insufficiency of tears (dry eyes) or if eyes become red or irritated.
• Corneal hypotony (decreased corneal sensitivity).
• Any systemic disease that is a contraindication to wearing contact lenses.
• Any active corneal infection (bacterial, fungal or viral).

Warnings: Problems with Contact Lenses and Lens Care Products Could Result in Loss of Vision

Different situations cannot always be used together; not all solutions are safe for use with all lenses. Use only solutions prescribed by the eyecare practitioner. Do not change lens care solutions without consulting the eyecare practitioner.

Eye Discomfort

Never wear contact lenses with bubbles present, or beyond the time recommended by the eyecare practitioner.

Eye Redness

Loss of Vision

Eye irritation or pain may not be corrected by the visual system for either near or far 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 poly-hema skirt of the lens may absorb this dye and become discolored. Whenever standard fluorescein is used in eyes, the dye should be removed immediately and a sterile saline solution used instead.

Care for a Sticking Lens

• Patients should be instructed to not store or reuse or “top off” old solution left in their lens case. Patients should be instructed that contact lenses are medical devices and parameters or lens type should not be changed without consulting an eyecare professional.

• Always contact the eyecare practitioner before using any medicine in the eyes.

Patients should be instructed to immediately consult his or her eyecare practitioner.

If the lens sticks (moves) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should be handled only by its edges to prevent damage to the delicate front surface of the lens.

Careful handling of contact lenses or reuse of contaminated lenses in the lens case can result in infection, vision loss or blindness. Never use the contaminated solution for lens care or the labeling of the contaminated bottle.

Water Activity

Maintenance of lens care product and lens case. Use of a commercially available lens care product.

Sterile unsupervised solutions, when used, should be discarded after the time specified in the label.

Loss of vision 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) as recommended by the eyecare professional.

Contamination (Reasons Not to Use)

DO NOT USE SynergEyes PS Hybrid Contact Lenses for Post Surgical Refractive Error and Trauma when:

9.0 to 9.7
0.8 to 0.9
5.0 mm
0.16-0.54 mm
11.0 to 12.0 mm
0.55mm
1.5-2.0 mm
Up to 1.000
N/A
5.0 N
100
5.0 N
276
* Unless otherwise indicated, contact: Moulded: ISO 18369-4:2006
† Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials, ISO 18369-4:2006
‡ Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials, ISO 18369-4:2006

Data 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) as recommended by the eyecare professional.

CONTAMINATION (Reasons Not to Use)

patients should be instructed to try to reposition the lens to be sure that the lens care product is not contaminated. If the lens care product is contaminated, the lens should be discarded.

The fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re TMPK the lenses in water. Contact lenses should be stored in the lens case and not left in contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended. Never air dry or re-”top” the lenses in water or contact lens solution. The lenses should be removed and the fitting evaluation should be completed with fresh, clean tissue is recommended.
A well fit lens provides for centration and minimal movement. The effects of lid interaction on blinking and gravity may result in lens dislocation during open eye wear. Patients must be cautioned: “when in doubt, take it out.” It is important that the wearer become accustomed to handling the lens, not simply the lens case. 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. If the lens has a smooth edge (60°), poor comfort (27%), poor vision (12%), or is easy to dislodge (10%), the lens 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.

FACEady care practitioners should be familiar with the signs of corneal deposits, which may include: redness of the eyes, photophobia; 1 loose interrupted suture and infiltrate; 1 abrasion of the cornea upon lens removal; 1 small red lesion on the cornea; 1 white or yellow soft material on the cornea; 1 red or yellow hard material on the cornea. The patient should be instructed to report any of these symptoms to their eyecare professional.

The best way to prevent and treat red eyes is to follow the instructions in the enzymatic cleaning labeling. Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. The patient should be instructed to closely follow the instructions on the hydrogen peroxide system labeling exclusively and should store the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the hydrogen peroxide solution. Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. The patient should be instructed to closely follow the instructions on the hydrogen peroxide system labeling exclusively and should store the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the hydrogen peroxide solution.

SUMMARY OF CLINICAL STUDY
A three month clinical study of the SynergEye PS Hybrid Contact Lens for Post Surgical Refractive Error and Trauma was conducted to evaluate safety, efficacy for vision correction in daily wear, and reaction to post-surgical refractive error including megalocornea, farsightedness, astigmatism, or 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 66 (87%) completed the study and 32 subjects (58 eyes) [42%] 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 ratio of 1.3 to 1.0. The average age of the completed and discontinued subjects was 41.3 years. Eight (6) adverse events were reported during the study for 4 completed subjects and 3 discontinued subjects. The adverse events included: 1) light pain sensitivity (photophobia); 2) episceral injection and irritation; 3) abrasion of the cornea upon lens removal; 1) superficial abrasion; 1) subject (2 eyes) with swelling of the cornea due to inadequate rinsing of hydrogen peroxide solution; 2) eye rubbing by patient; 2) eversion of silicone corneal lens. Thirty-two (32) subjects (58 eyes) [42%] were discontinued from the study. An additional 8 subjects were never dispensed lenses. The most common reasons for discontinuation were poor visual acuity (25.8%), blurred vision (15.4%), redness of the eyes (10.0%), non-compliance (10.0%), and handling difficulty (2.9%). Symptoms, Problems, and Complaints: For the complete study, no symptoms were reported at 46.2% of the dispensing visit or follow-up visit evaluated. For the study visit, no symptoms were reported at 28.5% of the dispensing visit or follow-up visit evaluated. Symptoms decreased over time for complex eyes but not for discontinued eyes. The most common symptoms reported were discomfort and awareness (26.4%), discomfort and awareness (65.5%), dryness and scratching (23-4%), itching and burning (9.3%), and variable vision (8.2%). Efficacy: Visual Acuities: At the end of the study, the visual acuities for the continued wear group were 20/20 or better (23.6%), 20/25 or less (69.8%), and 20/40 or better (81.3%). The visual acuity rates for discontinued subjects were 8.6%, 39.7%, 53.4%, and 70.7% respectively. Vision correction illustrated as expected with the corneal curvature from post-surgical conditions and under the contact lens contributing to the change. Three (3) complex 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 to the post-surgical visual acuity. Subjects in the study period the average daily wearing time reported by completed patients was 10 hours per day. Conclusion: SynergEyes PS Hybrid Contact Lenses for post-surgical refractive error and trauma involving provided satisfactory performance as expected. The higher than estimated determination rate was anticipated due to the nature of the subject population 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 SynergEye PS Hybrid Contact Lens for daily wear. Copies are available from: SynergEyes, Inc., Carlsbad, CA 92008 USA Telephone: (USA): 760-476-9410 or FAX: 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. During the first week, the patient should wear 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: 2 hours
Day 3 - Day 5: 5 hours
Day 6: Wear as eyecare practitioner allows during waking hours

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

Lenses Care Directions
1. Clean
While the recommended care products may be approved for a “No Rub” regimen, it is recommended that moderate cleaning pressure be applied to the lenses. Clean one lens first (always 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 recommended multipurpose disinfecting solution. Using a cotton tip applicator, 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 macules, and film from the lens surface. Place the lens into the correct lens chamber of the lens case. Then repeat the procedure for the second lens.

3. Check
Check for lens warpage and for debris or lint by looking at the lens chamber.

After cleaning and rinsing the lenses disinfect them by using the multipurpose solution. Follow the instructions provided on the multipurpose solution label. Note: SynergEye PS Hybrid Contact Lenses cannot be disinfected (thermally) disinfected.

In sterile 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 for a period of time, plan 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.

Contact lens care can be a source of bacterial growth. Patients should be instructed that after removing the lenses from the eye, they should not touch and rinse the lens case solution (sterile) 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 to use only the lubricating/rewetting solution that has been recommended by the eyecare practitioner. Patients should be instructed to handle the container with care to prevent cross contamination.

7. Lens Deposits and Use of Enzymatic Cleaning Procedure
Enzyme cleaning may be recommended by the eyecare practitioner. Use of enzymatic cleaning products 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. Enzymatic cleaning procedures are outlined on the lens solution labeling. Patients should be instructed to carefully follow the instructions in the enzymatic cleaning labeling.

5. Care for a Sticking (nonmoving) Lens
If the patient notices any of the above, they should be instructed to: IMMEDIATELY REMOVE THEIR LENSES and contact their eyecare practitioner. DO NOT attempt to help the lens back on their eye. Place the lens in the storage case and the patient should contact the eyecare practitioner. If the lens feels hot, or any other foreign objects on it, or the problem stops and the lenses appears undamaged, hold it in cool, clean, water and observe for several hours. If the sensation continues, the lens should not be worn.

After reapplication of the lens, if the problem continues, the patient should IMMEDIATELY remove the contact lens and consult the eyecare practitioner.

6. Care for a Dehydrated Lens
This is a problem with the SynergEye PS Hybrid Contact Lens may become dry/dull 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 insertion.

EMERGENCIES
If any 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.

HOW SUPPLIED
SynergEye PS Hybrid Contact Lens is supplied in a sterile plastic vial. NOTE: Do not dispense the lens if tamper 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 carrier package. The vial label is marked with the central equivalent base curve radius, diameter, 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.

Instructions
Use for one eye only by the practitioner. [ ночь
Identified by irradiation.
Storage, use instructions for use.
Use by Date
Valid until:
Up to 1 year after date of manufacture
 nor to be deconstructed
Up to 1 year after date of manufacture

Manufactured and Bottled by: SynergEyes, Inc., Carlsbad, CA 92008 USA
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