

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 the patient instructions that pertain to the patient's prescribed lens.

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.

The LifeStyle Company, Inc.

Wall, NJ 07719

PACKAGE INSERT

SGP 3™ (unifocan A)

Rigid Gas Permeable Contact Lenses for Daily Wear

Description

The **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** is available as a spherical contact lens. The lens material (unifocan A) is a (Fluorosilicon acrylate) copolymer with the following color additives depending on the desired tint: The blue lens is tinted with D&C Green No. 6. The green lens is tinted with a combination of D&C Green No. 6 and D&C Yellow No. 10. The brown and gray lenses are each tinted with unique combinations of D&C Green No. 6, Red No. 17, and (4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one). The **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens** is a hemispherical flexible shell which covers the cornea with the following dimensions:

- Chord diameter: 7.5 to 11.5 mm
- Center thickness: 0.07 mm to 0.30 mm
- Base curve: 6.00 mm to 8.50 mm
- Powers: +12.00 Diopters to -20.00 Diopters

The physical/optical properties of the lens are:

- Specific Gravity: 1.126
- Refractive Index: 1.481 n_D at 20°C
- Light Transmittance: 96 %
- Water Content: less than 0.5%
- Wetting Angle: < 20° (CLMA method)
- Oxygen permeability (D_k): 43.5×10^{-11} (cm² / sec) (ml O₂ / ml × mm Hg) at 35°C

* [Permeability determined by Dr. M. Poster at the College of Optometry using the oxygen flux method]

Actions

The **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** when placed on the cornea, acts as a refracting medium to focus light rays on the retina. The rigid lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

Indications (Uses):

The **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 4.00 diopters. The lens may be disinfected using a chemical disinfection system.

Contraindications (Reasons Not To Use)

DO NOT USE the **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** when any of the following conditions exist:

- If eyes become red or irritated
- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Insufficiency of lacrimal secretion (dry eyes)
- 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 which is to be used to care for the lens
- Any active corneal infection (bacterial, fungal, or viral)

WARNINGS:

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 THEIR EYECARE PRACTITIONER'S DIRECTION AND ALL LABELING INSTRUCTIONS FOR PROPER USE OF LENSES AND LENS CARE PRODUCTS, INCLUDING THE LENS CASE. EYE PROBLEMS, INCLUDING CORNEAL ULCERS CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.**
- **ALWAYS INSPECT LENSES CAREFULLY AFTER DISINFECTING AND CLEANING AND BEFORE INSERTING THEM IN THE EYE. INJURY CAN RESULT IF BROKEN, CRACKED, OR CHIPPED LENSES ARE INSERTED IN THE EYE.**
- **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 LENSES AND PROMPTLY CONTACT HIS OR HER EYECARE PRACTITIONER.**

PRECAUTIONS:

- **CAUTION:** Non-sterile. Clean and condition lenses prior to use.

Special Precautions for Eyecare Practitioners:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eyecare practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on the patient's ocular health 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.
- 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.

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

1. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
 2. Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
 3. Always use fresh unexpired lens care solutions.
 4. Always follow directions in the package inserts for the use of contact lens solutions.
 5. Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
 6. Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
 7. Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored). Prolonged periods of drying may damage the lenses. Follow the lens care directions for CARE FOR A DRIED OUT (DEHYDRATED) LENS if lens surface does become dried out.
 8. Inspect lenses before inserting them in the eye. The patient should be instructed how to inspect their lenses with examples of intact, broken, cracked, and chipped lenses.
- 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 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, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
 - Do not touch contact lenses with the 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 Instructions for the **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** and those prescribed by the eyecare practitioner.
 - Never wear lenses beyond the period recommended by the eyecare practitioner.
 - If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
 - Always handle lenses gently, do not bend the lenses, and avoid dropping them on hard surfaces.
 - Avoid all harmful or irritating vapors and fumes while wearing lenses.
 - Ask the eyecare practitioner about wearing lenses during water activities and other sports.
 - 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 EFFECTS:

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, or itching (irritation) or any other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, 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 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 body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should IMMEDIATELY remove the lenses and consult the eyecare practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING:

Conventional methods of fitting contact lenses do not apply to **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear**. For a detailed description of the fitting techniques, refer to the **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** Fitting and Information Guide, copies of which are available from:

The LifeStyle Company, Inc.
1800 Route 34 North, Ste 401
Wall, New Jersey 07719
Telephone (800) 622-0777
(732) 972-8585

PREPARING AN RGP LENS FOR FITTING:

Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens. Lenses should be surface cleaned and disinfected in the manner described in the section entitled "Lens Care Directions" prior to wearing.

WEARING SCHEDULE:

THE WEARING AND REPLACEMENT SCHEDULES SHOULD BE DETERMINED BY THE EYECARE PRACTITIONER. Patients tend to overwear the lenses initially. The eyecare practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eyecare practitioner, are also extremely important.

The **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** is indicated for daily wear. The maximum suggested wearing time for the lenses is:

Day	Hours	Day	Hours
1	[4]	6	[9]
2	[5]	7	[10]
3	[6]	8	[11]
4	[7]	9	[12]
5	[8]	10 and after	all waking hours

Studies have not been completed to show that the **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** is safe to wear during sleep.

LENS CARE DIRECTIONS:

Eyecare practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (First 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. Never re-use solution.
- Use the recommended system of lens care, 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.
- Always carefully inspect lenses for chips, cracks, or breakage before inserting them in the eye. Discomfort and injury may result if broken, cracked, or chipped lenses are placed in the eye.

- Do not use saliva or anything other than the recommended solutions 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 a schedule prescribed by your eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- The eyecare practitioner should recommend a care system that is appropriate for the **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear**. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Chemical Disinfecting Method:

- Clean one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, disinfect lenses using the system recommended by the manufacturer and/or eyecare practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. Lenses stored longer than 12 hours may require cleaning, rinsing and disinfection again before use. The patient should consult the package insert or the eyecare practitioner for information on storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with fresh disinfecting/storage solution. Replace lens case at regular intervals.
- Do not heat the disinfecting solution and lenses.

LENS CASE CLEANING AND MAINTENANCE:

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with rinsing solution, and allowed to air dry. Lens cases should be replaced at regular intervals.

CARE FOR A STICKING LENS:

If the lens sticks (stops moving), the patient should be instructed to apply 1 to 2 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. If nonmovement of the lens continues after 5 minutes, the patient should immediately consult the eyecare practitioner.

EMERGENCIES:

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patients should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

HOW SUPPLIED:

Each lens is supplied in an individual plastic case. The case is labeled with the base curve, dioptric power, add power, diameter, center thickness, tint, and lot number.

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing the **SGP 3™ (unifocan A) Rigid Gas Permeable Contact Lens for Daily Wear** should be reported to:

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