The LifeStyle Company, Inc.
Wall, NJ 07719

PACKAGE INSERT

SGP™ (telefocon A) and SGP II™ (telefocon B)
Rigid Gas Permeable Contact Lenses for Daily Wear

Description

The SGP™ (telefocon A) or SGP II™ (telefocon B) Rigid Gas Permeable Contact Lenses for Daily Wear are available as non-spherical contact lenses. The lens material (telefocon A or telefocon B) is a (Methylmethacrylate-silicon) copolymer with the following color additives depending on the desired tint. The blue lens is tinted with D&C Green No. 4 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 (1,2,4-trimethyl-5-methoxy-2,4-dihydro-5-chem-3H-pyrazol-1-one). The SGP™ (telefocon A) or SGP II™ (telefocon B) Rigid Gas Permeable Contact Lenses are a hemispherical flexible shell which covers the central corneal dimensions:

- Chord diameter: 7.5 to 11.5 mm
- Center thickness: 0.05 mm to 0.50 mm
- Base curve: 6.00 mm to 8.50 mm
- Powers: +12.00 Dipters to -20.00 Dipters

The physical/ optical properties of the lens are:

- Specific Gravity: 1.126
- Refractive Index: 1.475 ± 0.004 at 20°C
- Light Transmittance: clear: 98.5 %
- tinted: 96 %
- Water Content: less than 0.5%
- Wetting Angle: < 30° (CLMA method)
- Oxygen permeability (Dk): SGP: ~22.0 × 10⁻¹¹ cm² ml O₂ / ml mm Hg at 35°C
- Oxygen permeability (Dk/t): SGP II: 43.5 × 10⁻¹¹ cm² ml O₂ / ml mm Hg at 35°C

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.

CAUTION: Do not use these lenses if you are sensitive to the following care regimen and safety precautions:

- If eyes become red or irritated
- Any active corneal infection (bacterial, fungal, or viral)
- Allergy to any ingredient, such as mercury or Thimerosal in a contact lens solution which is to be used to care for the contact lens.
- If eyes become red or irritated
- Residual proteins or corneal stromal infiltrates.
- Non-sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Avoid all harmful or irritating vapors and fumes while wearing contact lenses.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- Avoid all 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.
- 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.
- Always handle lenses gently, do not bend the lenses, and avoid settling.
- If non-sterile unpreserved solutions are used, the lenses may be damaged.
- If the lens slips (stops moving) on the eye, follow the recommended care directions for 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.
- If contact lenses are worn overnight, they damage the eye.
- 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.
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- If contact lenses are worn overnight, they damage the eye.
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, the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinf orate the lenses; then insert them. After reinserter, 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™ (telefcon A) or SGP II™ (telefcon B) Rigid Gas Permeable Contact Lens for Daily Wear. For a detailed description of the fitting techniques, refer to the SGP™ (telefcon A) or SGP II™ (telefcon B) 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 overt wear 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™ (telefcon A) or SGP II™ (telefcon B) Rigid Gas Permeable Contact Lens for Daily Wear is indicated for daily wear. The maximum suggested wearing time for the lenses is:

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Studies have not been completed to show that the SGP™ (telefcon A) or SGP II™ (telefcon B) 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 Contact 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 iritis may result if broken, cracked, or chipped lenses are placed in the eye.
- Do not use saliva or any 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 disinfest 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™ (telefcon A) or SGP II™ (telefcon B) 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, disinfest 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. Lenses 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.

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

REPORTING OF ADVERSE REACTIONS:
All serious adverse experiences and adverse reactions observed in patients wearing the SGP™ (telefcon A) or SGP II™ (telefcon B) Rigid Gas Permeable Contact Lens for Daily Wear should be reported to:
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