

- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- If eye becomes red or irritated.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:

Problems with contact lenses and contact lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's directions and labeling instructions for proper use of lenses and lens care products, including the lens case.

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/her eye care practitioner.

PRECAUTIONS

CAUTION: NONSTERILE.

CLEAN AND CONDITION LENSES PRIOR TO USE.

SPECIAL PRECAUTIONS FOR EYE CARE PRACTITIONERS

Due to the small number of patients enrolled in the clinical investigation of the lenses, all refractive powers, design configurations, or lens parameters available in the lens materials are not evaluated in significant enough 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, wet ability, central and peripheral thickness, and optical 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.

Aphakic patients should not be fitted with the OP-2™ (lotifocoon B), OP-3™ (lotifocoon A), OP-6™ (lotifocoon C) until the determination is made that the eye has healed properly. Fluorescein, a yellow dye, can be used while the lenses are on the eye. Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lenses or have someone else available who can remove the lenses for him/her. Eye care practitioners should instruct the patient to remove the lens immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct the patients about the following care regimen and safety precautions. Different solutions cannot always

- Different solutions cannot always be used together and not all solutions are safe to use with all lenses. Use only recommended solutions.
- Never use solutions recommended for hard lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on the product labeling for use in both heat and chemical disinfection.
- Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat.
- Always use fresh unexpired lens care solution.
- Always follow directions in the package insert for the use of contact lens solutions.
- Use only a chemical lens care system. Use of a thermal (heat) care system can cause the OP-2™ (lotifocoon B), OP-3™ (lotifocoon A), OP-6™ (lotifocoon C) lenses to warp.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva 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 (stored).
- If the lens sticks (stops moving) on the eye, follow the recommended instructions 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/her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in the eye or on the lenses.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the *Patient Instructions* for the OP-2™ (lotifocoon B), OP-3™ (lotifocoon A), OP-6™ (lotifocoon C) Contact Lenses and those prescribed by the eye care practitioner.
- Never wear the lenses beyond the period recommended by the eye care 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 carefully and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during sporting events.
- 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.
- Do not touch lens with fingernails.
- Always contact your eye care practitioner before using any medicine in the eye.
- Always inform your employer of being a contact

Lens Care Table

<u>Product Purpose</u>	<u>Chemical System</u>
Chemical (Not Heat) Clean	LOBOB OPTIMUM® Extra Strength RGP Cleaner
Rinse, Disinfect And Storage	LOBOB OPTIMUM® Cleaning/Disinfecting/ Storage
Wetting, Lubricate/Rewet	LOBOB OPTIMUM®/ Wetting/Rewetting
Enzyme	Any Recommended Solution

LOBOB OPTIMUM® is the registered name of Lobb Laboratories, Inc.

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.

Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with the recommended saline or disinfecting solution to remove the cleaning solution, mucus and film from the lens surface, and put the lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens. After cleaning, disinfect the lenses using the system recommended by the manufacturer and/or eye care practitioner. To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If the lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on the storage of lenses. Always keep the lenses immersed in a recommended disinfection solution/conditioning solution when the lenses are not being worn. If you discontinue wearing your lenses, but plan to begin wearing them again after a few weeks, ask your eye care practitioner for a recommendation on how to store your lenses. After removing the lenses from the lens case, empty and rinse the lens storage case with the solution as recommended by the lens case manufacturer, then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your eye care practitioner. Your eye care practitioner may recommend a lubricating/wetting solution for your use. Lubricating/wetting solutions can be used to wet (lubricate) your lenses while wearing them to make them more comfortable. The OP-2™ (lotifocon B), OP-3™ (lotifocon A), OP-6™ (lotifocon C) Rigid Gas Permeable Lenses cannot be heat (thermally) disinfected.

CHEMICAL (NOT HEAT) DISINFECTION

Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution. After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care system recommended by the lens manufacture or eye care practitioner. Thoroughly rinse the lens with a fresh solution recommended for rinsing

before inserting and wearing or follow the instructions on the disinfection solution labeling. Do not heat the disinfecting solution and the lenses. Leave the lenses in the unopened storage case until ready to put on the eyes. Enzyme cleaning may be recommended by the eye care 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 patient's 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. For enzyme cleaning, the patient should carefully follow the instructions on the enzymatic cleaning label.

LENS CASE CLEANING AND MAINTENANCE

Contact lenses can be a source of bacterial growth. Lens cases should be emptied, cleaned and rinsed with solutions recommended by the lens case manufacturer and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacture or your eye care practitioner.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or cannot be removed, the patient should be instructed to apply 2-3 drops of the recommended lubricating/wetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues after 2-3 minutes, the patient should immediately consult the eye care practitioner.

EMERGENCIES

The patient should be informed that if any chemicals (household products, gardening solution, laboratory chemicals, etc.) are splashed into the eyes the patient should FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied non-sterile in a plastic lens storage case. The case is labeled with the base curve, dioptic power, diameter, center thickness, color, material, lot number, and expiration date.

REPORTING ADVERSE REACTIONS

All serious adverse experiences and reactions observed in patients wearing OP-2™ (lotifocon B), OP-3™ (lotifocon A), and OP-6™ (lotifocon C) Rigid Gas Permeable Contact Lenses should be reported to:

Stellar Contact Lens Ltd.
8131 Tripp Avenue
Skokie, IL 60076
(800)729-9503

lens wearer. Some jobs may require the use of eye protection 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 regular follow-up schedule.

ADVERSE REACTIONS

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

- Eyes stinging, burning, itching, (irritation) or other eye problems.
- Comfort is less than when first placed on the eye.
- Feeling of something in the eye (foreign body, scratched area).
- Excessive watering (tearing) of the eye or 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/she should be instructed to immediately remove the lens.

If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, do not put the lens back in the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or if the problem stops and the lens appears to be undamaged, the patient should thoroughly clean, rinse, and disinfect the lens; then reinsert it. After reinsertion, if the problem continues, the patient should immediately remove the lenses and consult the eye care practitioner. When any of the above problems occur, a serious neovascularization or iritis may be present. The patient should be instructed to keep the 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 rigid contact lenses apply to the OP-2™ (lotifocon B), OP-3™ (lotifocon A), OP-6™ (lotifocon C) Rigid Gas Permeable Contact Lenses. For a detailed description of the fitting techniques, refer to the *Professional Fitting and Information Guide*, copies of which are available from Stellar Contact Lens Ltd., 8131 Tripp Avenue, Skokie, IL 60076.

PREPARING AN RGP LENS FOR FITTING

Prior to dispensing the final lens to the patient, they should be cleaned, rinsed and disinfected with the recommended solution, and soaked in the disinfecting solution overnight. Then follow the *Basic Lens Care General Instructions*.

WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to overwear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular check-ups, as determined by the eye care practitioner, are also extremely important.

The OP-2™ (lotifocon B), OP-3™ (lotifocon A), OP-6™ (lotifocon C) Rigid Gas Permeable Contact Lenses are indicated for daily wear. The maximum suggested wearing time for these lenses is:

Day	Hours
1	5
2	6
3	7
4	8
5	9
6	up to 10
7	up to 15
8	all waking hours
9	all waking hours
10	all waking hours

Studies have not been completed to show that OP-2™ (lotifocon B), OP-3™ (lotifocon A), OP-6™ (lotifocon C) Rigid Gas Permeable Contact Lenses are safe to wear during sleep.

LENS CARE DIRECTIONS

Eye care practitioners should review 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 (To First Clean and Rinse, Then Disinfect the Lenses).

Always wash, rinse and dry hands before handling contact lenses. Always use fresh, unexpired lens care solutions. Use the recommended chemical system of lens care and carefully follow instructions on the 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 the solution labeling.

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, enzyme (as recommended by the eye care practitioner) and disinfect the lenses according to the schedule by the eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection. The lens care products listed below are recommended for use with the the OP-2™ (lotifocon B), OP-3™ (lotifocon A), OP-6™ (lotifocon C) Rigid Gas Permeable Contact Lenses. Contact Lens Eye Care Practitioners may recommend alternate products that are appropriate for the patient's use with his/her lenses.

PACKAGE INSERT

OP-2™ (lotifocon B), **OP-3™** (lotifocon A), **OP-6™** (lotifocon C)
RIGID GAS PERMEABLE CONTACT LENS;
Spherical, Aspherical and Toric Lenses for:
Myopia, Hyperopia, Aphakia and Astigmatism

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

CAUTION – Federal law prohibits dispensing without a prescription.

DESCRIPTION: OP-2™ (lotifocon B), **OP-3™** (lotifocon A), **OP-6™** (lotifocon C) Rigid Gas Permeable Contact Lenses are available as spherical, aspherical and toric lenses in clear, blue, green, gray, and brown. The lens materials **OP-2™** (lotifocon B), **OP-3™** (lotifocon A), **OP-6™** (lotifocon C) are a fluorosilicone acrylate polymer. The blue tinted lens contains the color additive D&C Green Dye #6. The gray tinted lens contains D&C Green #6 and D&C Red #17. The green tinted lens contains D&C Green #6 and Solvent Yellow #18. The brown tinted lens contains Solvent Yellow #18, D&C Red #17, D&C Violet #2 and D&C Green #6. The lenses are a hemispheric shell of the following dimensions:

Diameter	7.50 mm to 10.50 mm
Base Curve	5.10 mm to 9.00 mm
Distance Power	+10.00 to -20.00 D
Ctr. Thickness	0.10 mm to 1.00 mm
Toric Axis	Plano to 180°
Power	+2.50 to -2.50

PHYSICAL/OPTICAL PROPERTIES

OP-2™ (lotifocon B)

Hardness	87.0 (Shore Units)
Water Content	<1%
Wetting Angle	17°
O ₂ Permeability	15.9 x 10 ⁻¹¹ (cm ² /sec)
At 35°	(ml O ₂ /ml x mmHg)
Refractive Index	1.467
Light transmission	CL 87%, BL 86%, GY 85%, GN 86%, BRN 79%

Specific Gravity 1.115
Surface Character Hydrophobic

OP-3™ (lotifocon A)

Hardness	86.0 (Shore Units)
Water Content	<1%
Wetting Angle	21°
O ₂ Permeability	30 x 10 ⁻¹¹ (cm ² /sec)
At 35°	(ml O ₂ /ml x mmHg)
Refractive Index	1.457
Light transmission	CL 88%, BL 86%, GY 85%, GN 85%, BRN 79%

Specific Gravity 1.115
Surface Character Hydrophobic

OP-6™ (lotifocon C)

Hardness	86.0 (Shore Units)
Water Content	<1%
Wetting Angle	26°
O ₂ Permeability	61.5 x 10 ⁻¹¹ (cm ² /sec)
At 35°	(ml O ₂ /ml x mmHg)
Refractive Index	1.447
Light transmission	CL 87%, BL 85%, GY 85%, GN 86%, BRN 78%

Specific Gravity 1.113
Surface Character Hydrophobic
(O₂ permeability was measured by the Polarographic method of Irving Fatt PhD.)

ULTRA-VIOLET ABSORBER

The **OP-3™** (lotifocon A) and **OP-6™** (lotifocon C) materials are available with a UV absorber in Blue tint only. The UV absorber has been incorporated as an additive into the matrix of the polymer blocking up to 96% of the ultra-violet below 380nm.

WARNING: Contact lenses with a UV absorber are not a substitute for protective UV absorbing eyewear.

ACTION

OP-2™ (lotifocon B), **OP-3™** (lotifocon A), **OP-6™** (lotifocon C) Rigid Gas Permeable Contact Lenses when placed on the cornea acts as a refracting media to focus light rays on the retina. The toric lens provides a more even surface over the highly uneven cornea and thus helps to focus light rays on the retina.

INDICATIONS (USES)

OP-2™ (lotifocon B), **OP-3™** (lotifocon A), **OP-6™** (lotifocon C) Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lenses may be worn by persons who may exhibit astigmatism of 2.50 diopters or less that does not interfere with visual acuity.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the **OP-2™** (lotifocon B), **OP-3™** (lotifocon A), **OP-6™** (lotifocon C) Rigid Gas Permeable Contact Lenses when any of the following conditions exists:

- Acute and subacute inflammation between the lens and the iris and the cornea or the anterior chamber of the eye.
- Any disease, injury or abnormality which affects the cornea, conjunctiva or eyelids.
- Any active corneal infection: bacterial, fungal or viral.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypesthesia (reduced corneal sensitivity), if not aphakic.
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- Allergy to any ingredient such as mercury or thimerosal, in a solution which must be used to care for contact lenses.