

## PACKAGE INSERT

**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 the patient upon request. The eyecare practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lenses.

**CAUTION:** Federal Law Prohibits Dispensing Without A Prescription.

### SA-32 (kolfocon B)

Rigid Gas Permeable Spherical, Aspherical and Toric Contact Lenses for Nearsightedness (Myopia), Farsightedness (Hyperopia) and Astigmatism

**DESCRIPTION:** The SA-32 (wilofoccon B) Rigid Gas Permeable Contact Lens is available as a spherical, aspherical, astigmatic (toric) lens. The lens material, kolfocon B, is a silicone-acrylate copolymer which may contain one or more of the following color additives: Phthalocyanine Blue, Phthalocyanine Green, D&C Green 6, D&C Violet 2, D&C Red 17, and/or Solvent Yellow 18. The SA-32 (wilofoccon B) Contact Lens is a hemispherical shell of the following characteristics:

#### LENS PARAMETERS AVAILABLE:

Diameter	6.5 to 11.5 mm
Center Thickness	0.05 to 0.30 mm (minus power lenses) 0.10 to 0.70 mm (plus power lenses)
Base Curve	6.50 to 9.00 mm
Powers	-20.00 to +20.00 Diopters
Aspheric Eccentricity	0 to 1.5 (oblate to prolate)
Peripheral Curves	0.1 to 10 mm flatter than base curve
Toric Lens Axis	1° to 180° in 1° steps
Toric Cylinder Power	0.50 to 4.00 diopters

#### PHYSICAL PROPERTIES:

Specific Gravity	1.101 g/cc
Refractive Index	1.467
Light Transmittance (380 to 780 nm)	
Clear	>95% T
Blue	>87% T
Wetting Angle (CLMA)	<25°
Water Content	<1%
Hardness (Shore D)	86
Oxygen Permeability (Fatt Units, 1983)	32

**ACTIONS:** The SA-32 (kolfocon B) Rigid Gas Permeable Spherical, Aspherical and Toric Contact Lens when placed on the cornea, acts as a refracting medium to focus light rays on the retina. The toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

**INDICATIONS (USES):** The SA-32 (kolfocon B) Rigid Gas Permeable Spherical, Aspherical and Toric Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in non-aphakic persons with non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

**CONTRAINDICATIONS (REASON NOT TO USE):** DO NOT USE the SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lens when any of the following conditions exist:

1. Acute or subacute inflammation or infection of the anterior chamber of the eye.
2. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids.
3. Severe insufficiency of lacrimal secretion (dry eyes).
4. Corneal hypoesthesia (reduced corneal sensitivity) if not aphakic.
5. Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
6. Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
7. Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the SA-32 (kolfocon B) Rigid Gas Permeable Spherical, Aspherical and Toric Contact Lenses.
8. Any active corneal infection (bacterial, fungal or viral).
9. If eyes become red or irritated.

**WARNINGS:** Patients should be advised of the following warnings pertaining to contact lenses: Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's directions 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. 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 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 immediately remove the lenses and promptly contact his or her eye care practitioner.

#### PRECAUTIONS:

**CAUTION:** Non-sterile. 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 all 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 eye care 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 eye care practitioner. Fluorescein, a yellow dye, may be used in the fitting of SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical, Toric and Bifocal Contact Lenses and for the evaluation of corneal integrity.

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

Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Use only recommended solutions. Do not heat the wetting/soaking solution and lenses. Keep away from extreme heat. Always use fresh unexpired lens care solutions. Always follow directions in the package inserts for the use of contact lens solutions. Use only a chemical lens care system. Use of a heat (thermal) care system can damage by warping the SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lenses. 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). Prolonged periods of drying will reduce the ability of the lens surface to return to a wettable state. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if the lens surface does become 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 eye care 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-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 on the lenses may occur, causing distorted vision and/or injury to the eye. Carefully follow the handling, insertion, removal, cleaning, disinfection, storing and wearing instructions in the Patient's Instructions for the SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lens and those prescribed by the eyecare practitioner. Never wear lenses beyond the period recommended by the eyecare practitioner. Avoid all harmful or irritating vapors and fumes when wearing lenses. Always handle lenses carefully and avoid dropping them. 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:** The patient 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.
- Feeling of something in the eye such as a foreign body or scratched area.
- Excessive watering (tearing) of the eye.
- 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 YOUR 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 your eye. Place the lens in the storage case and contact your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign object on it, or if the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse and disinfect the lenses, then reinsert them. If the problem continues, the patient should IMMEDIATELY remove the contact 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 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 SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lens. For a description of fitting techniques, refer to the Fitting Guide for SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lenses. Copies are available from: The Lagado Corporation, 2890 South Tejon Street, Englewood, CO 80110

**WEARING SCHEDULE:** The SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lenses are indicated for daily wear. The maximum suggested wearing time for the lenses is:

**DAILY WEAR (LESS THAN 24 HOURS WHILE AWAKE)**

Day	1	2	3	4	5	6	7	8 (and after)
Hours	5	6	7	8	9	10	15	All hours awake

Studies have not been completed to show that the SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lens is safe to wear during sleep. The wearing and replacement schedule 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 check-ups, as determined by the eyecare practitioner, are also extremely important.

**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 (To First Clean and Rinse, Then Disinfect Lenses)  
Basic Instructions:

Always wash, rinse, and then dry hands before handling contact lenses. Always use fresh unexpired lens care solutions. 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. 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 enzyme (as recommended by the eyecare practitioner) and disinfect lenses according to the schedule prescribed by the eyecare practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

The lens care products listed below are recommended by the Lagado Corporation for the use with SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lenses. Eyecare practitioners may recommend alternate products that are appropriate for the patient's use with his or her lenses.

Lens Care Table.	
<b>Product Purpose</b>	<b>Lens Care System</b> (chemical - not heat)
Clean	Lobob Optimum Extra Strength Cleaner
Rinse	Sterile Saline
Disinfect and Store	Lobob Optimum Cleaning, Disinfecting and Storage Solution
Lubricate/Rewet	Lobob Wetting and Rewetting Drops
Enzyme	ProFree Enzymatic Cleaner

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 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 lenses using the system recommended by the manufacturer and/or the eyecare practitioner. To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eyecare practitioner for information on storage of lenses. After removing lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens care manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals as recommended by the lens care manufacturer or eyecare practitioner. Eyecare practitioners may recommend a lubricating/rewetting solution which can be used to wet (lubricate) lenses while they are being worn to make them more comfortable. SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lens cannot be heat (thermally) disinfected. Chemical 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 disinfection solution in the care regimen recommended by the lens manufacturer or the eyecare practitioner. When using hydrogen peroxide lens care systems (for office sterilization only), lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling. Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfections solution labeling. Do not heat the disinfection solution and lenses. Leave the lenses in the unopened storage case until ready to put on the eyes. 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 in 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 in the enzymatic cleaning labeling.

**LENS CASE CLEANING AND MAINTENANCE:** Contact lens cases can be a source of bacterial growth. Lens cases should be emptied, cleaned, 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 manufacturer or the eyecare practitioner.

**CARE FOR A STICKING (NONMOVING) LENS:** If a lens sticks (stops moving) or cannot be removed, the patient should be instructed to 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. If nonmovement of the lens continues after 30 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 patient should: **FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

**HOW SUPPLIED:** The lens is packaged non-sterile in a flat pack. The container is marked with the base curve, diopter power, diameter, center thickness, color, lot number and expiration date.

**REPORTING ADVERSE REACTIONS:** All serious adverse experiences and adverse reactions observed in patients wearing SA-32 (kolfocon B) rigid Gas Permeable Spherical, Aspherical and Toric Contact Lenses must be immediately reported to the manufacturer.

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