

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.