

Kontur 55 Sphere and Kontur 55 Toric

Package Insert

Description

The *Kontur 55* (methafilcon A) hydrophilic contact lens is a hemispherical shell of approximately 15.0 mm. chord diameter, 0.10 to 0.60 mm. center thickness, cylinder power range of -0.75 to -5.00 diopters, and base curve of 8.30 to 8.90 diopters. The lens consists of 45% methafilcon A and 55% water by weight when immersed in normal saline. The material has a refractive index of 1.415, specific gravity of 1.09, and an oxygen permeability of $18.83 \times 10^{-11} (\text{cm}^2/\text{sec}) \text{ ml O}_2/\text{ml} \times \text{mm}$

Hg at 25° C as measured by Schema Versatae Model 920 connected to a polarographic cell. The surface character or the lens is hydrophilic. The light transmittance is 98.8%.

Actions

The astigmatic (toric) lens provides a more even surface over the uneven astigmatic cornea and thus helps to focus light rays on the retina.

Indications

The *Kontur 55 Sphere* contact lens is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons with refractive astigmatism of 1.50 diopters or less that does not interfere with visual acuity. The lens ranges in power from -20.00 diopters to +20.00 diopters.

The *Kontur 55 Toric* contact lens is indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic, hyperopic or for refractive astigmatism not exceeding 5 diopters and that does not interfere with visual acuity. The lens ranges in powers from -20.00 to +10.00 diopters.

Lenses of unusually high refractive power, i.e., greater than -20.00 to +12.00 D in phakic eyes and greater than +20.00 D in aphakic eyes, are not usually evaluated in significant numbers during the clinical investigation of the lens, due to the small number of patients needing such extreme correction.

Consequently, when prescribing lenses of greater than -20.00 to +12.00 D for phakic eyes, or greater than +20.00 D for aphakic eyes, special consideration must be given to all characteristics of the lens that can affect 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 must be carefully weighed against the patient's need for refractive correction, and the patient's continued ocular health should be carefully monitored.

Contraindications

Kontur 55 contact lenses are contraindicated by the presence of any of the following conditions:

1. Acute and subacute inflammations of the anterior segment of the eye.
2. Any eye disease which affects the cornea or conjunctiva.
3. Insufficiency of lacrimal secretion.
4. Corneal hypoesthesia.
5. Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
6. Any active corneal infections; bacterial, fungal, viral, or purulent.
7. Allergy to any ingredient such as mercury or thimerosal in a solution which must be used to care for the lens.

Adverse Reactions

Serious corneal damage may result from wearing a lens which has been soaked in conventional hard lens solution. Eye irritation may occur within a short time after putting on a lens stored in a solution of improper pH of tonicity. Removal of the lens will relieve the irritation. Excessive tearing or redness, unusual eye secretions, reduced visual acuity, blurred vision, halos of light in the field of vision, and light sensitivity are not normal; if these symptoms occur, the patient should be examined by an eye care practitioner to determine the cause.

Warnings

Medicaments and Eye Drops:

The *Kontur 55* contact lens must be stored only in the recommended solutions. No ophthalmic solutions or medicaments should be used unless directed by your eye-care practitioner. Never use conventional hard lens solutions. Only the recommended disinfectant soaking solutions should be used. Lubricating solutions (see recommended list of solutions) may be used on the *Kontur 55* contact lens.

Abrasions and Infections:

If the lens becomes less comfortable than when it was first placed on the cornea, or the vision becomes less clear, this may indicate the presence of a foreign body, an improperly cleaned lens, or the lens or lenses may be in the incorrect eye. The lens, or lenses, should be removed immediately, and examined. If any corneal abrasion, ulceration, irritation or infection is present, an eye care practitioner should be consulted immediately.

Visual Blurring:

When visual blurring occurs, the lens must be removed and cleaned. If visual blurring continues, consult your eye care practitioner immediately.

Wearing restrictions:

The *Kontur 55* contact lens should be removed before sleeping or swimming or in the presence of noxious and irritating vapors.

Precautions

Lens Handling:

Patients must wash and rinse hands thoroughly and dry with a lint free towel before handling the lenses. Cosmetics, lotions, soaps, and creams must not come into contact with the lenses, since eye irritation or lens discoloration may result. If hair spray is used while the lenses are being worn, the eyes must be closed until the spray has settled.

Fluorescein

Never use fluorescein while wearing the lens because the lens will become discolored. Whenever fluorescein is used, flush the eyes with normal saline solution and wait at least one hour before replacing the lens. Too early replacement may allow the lens (or lenses) to absorb residual fluorescein irreversibly.

Patient must adhere to the recommended daily care regimen of *Kontur 55* contact lenses. Failure to follow this procedure may result in development of serious ocular infections.

Storage:

Kontur 55 contact lenses must be stored in the recommended solutions. If left exposed to air, the lenses will dehydrate. If a lens dehydrates, it should be soaked in the recommended solution a minimum of four hours.

Cleaning and Disinfection:

Kontur 55 contact lenses must be cleaned and disinfected daily. One procedure does not replace the other. **CLEANING** is necessary to remove mucus and film from the lens surface. This can be accomplished by using the recommended solutions on a daily basis. Excessive deposits may damage the lens; therefore, if this occurs, evaluation of the lens care procedure should be made with the eye practitioner.

CHEMICAL DISINFECTION of the contact lens is necessary to remove potentially harmful micro-organisms from the lens before placing the lens on the eye. This can be accomplished by using the recommended solutions. *Kontur 55* contact lenses must be cleaned and rinsed daily, or after wearing, with the recommended cleaning solution and saline rinse. The lens case must be emptied and refilled with fresh recommended storage disinfection solution prior to disinfecting the lenses. Fresh storage and disinfection solution must be used daily for storage and disinfecting the lenses.

WARNING: HEAT DISINFECTION SHOULD NOT BE USED WITH THE KONTUR 55 CONTACT LENS.

Wearing Schedule:

Conventional methods of fitting contact lenses do not apply to hydrophilic contact lenses. For a detailed description of the fitting technique, refer to an appropriate hydrophilic contact lens professional fitting guide, copies of which are available from Kontur Contact Lens Co., Inc., 642 Alfred Nobel Dr., Hercules, CA, 94547

The wearing schedule should be determined by the eye care practitioner.

Maximum wearing Time	
Day	Continuous Hours
1	6
2	8
3	10
4	12
5	14
6	All waking

There may be a tendency for the patient to overwear the lenses initially. Therefore, the importance of adhering to the initial daily wearing schedule should be stressed to the patient. Care must be taken on the initial visit to assure that the patient is supplied with a chemical disinfection patient care kit and fully understands all care and handling instructions for the lenses. As with any contact lens, regular recall visits are necessary to assure patient health and compliance with instructions.

How Supplied

Each lens is supplied sterile in a glass vial containing sterile normal saline solution, buffered with sodium bicarbonate USP. The glass vial is marked with the base curve, dioptric power, diameter, manufacturing lot number, and expiration date.

To assure proper lens care and handling, each *Kontur 55* patient must be supplied with the *Kontur 55* Wearer's Guide.

Recommended Care Solutions

The recommended accessory products required for the chemical disinfection, cleaning and storage of *Kontur 55* contact lens consist of the following:

1. Cleaning – PLIAGEL, LENS PLUS DAILY CLEANER, MIRAFLW DAILY CLEANER
2. Rinsing - OPTI-FREE, UNISOL, LENS PLUS
3. Disinfection - OPTI-FREE, RE-NU, AOSEPT, AOSEPT CLEAR CUT
4. Lubricating Solutions - CLERZ-2

* Other solutions and disinfection systems are available for use with soft (hydrophilic) contact lenses. Follow your eye care professional's recommendations for the lens care system which best suits your needs.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE ON OR BY THE ORDER OF A LICENSED PRACTITIONER

Manufactured and distributed by:

KONTUR CONTACT LENS CO., INC.
642 Alfred Nobel Dr.
Hercules, California 94547