

PACKAGE INSERT

OPERM™ F60 (oxyflufocon A)

Rigid Gas Permeable Contact Lenses for Daily Wear
Shipped Dry; or Wet Shipped in Solution

IMPORTANT

Please read carefully and keep this information for future use.

WARNING: The practitioner should provide this warning to the patient.

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your contact lenses and lens care products, including the lens case.

Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.

Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.

EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, OR REDNESS OF THE EYE, OR OTHER PROBLEMS WITH YOUR EYES, IMMEDIATELY REMOVE YOUR LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

OPERM™ F60 (oxyflufocon A)

Rigid Gas Permeable Contact Lenses for Daily Wear

Spherical, Aspheric, Bifocal, Toric contact lenses for:

- Nearsightedness (myopia).
- Farsightedness (hyperopia).

DESCRIPTION

OPERM™ F60 (oxyflufocon A) rigid gas permeable contact lenses for daily wear are available as lathe cut firm and wetttable non-hydrophilic contact lenses made of a silicone-acrylate/fluorocarbon-acrylate polymer with spherical, aspheric, bifocal or toric anterior and/or posterior; or, bitoric surfaces in clear and tinted versions. The posterior curve is selected so as to properly fit an individual eye and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

The lens has the following dimensions:

Chord diameter	7.0 mm – 15.0 mm
Center Thickness	0.07 mm -.065 mm
Base Curve	5.0 mm – 9.0 mm
Lens Powers	-20.00 - + 12.00 Diopters

OPERM™ F60 rigid gas permeable lenses may offer a handling tint for locating the lens. This product may be plasma treated.

PHYSICAL PROPERTIES

OPERM™ F60 (oxyflufocon A)

Refractive Index	1.45
Light Transmittance+	> 90% above 480 nm
Wetting Angle (Receding Angle)++	19.2°
Wetting Angle (Contact Angle)+++	61°
Specific Gravity	1.13
Hardness (Shore D)	84
Water Content	< 1%
Oxygen Permeability*	62 x 10 ⁻¹¹ Dk at 35o C
Tint D & C Green No. 6	

+ Determination of the Spectral and Light Transmittance, ISO 8599:1994

++ Adapted from: A New Method for Wetting Angle Measurement; Madigan, et. al., International Eye care, 01/1998, vol. 2, no. 1, p. 45

+++ Sessile Drop Technique per ANSI Z80.20. 8.11

*(cm²/sec) (mL O₂) / (mL x mm Hg) Irving Fatt, PhD Method

ACTION

OPERM™ F60 rigid gas permeable spherical, aspheric, toric and bifocal contact lenses are intended for daily wear only.

When placed on the human cornea, the OPERM™ F60 rigid gas permeable contact lens acts as a refracting medium to focus light rays on the retina.

The toric lens provides for the individual meridional power requirements of the astigmatic eye. In the bifocal lens, the distance or near power prescription is provided in a small area with the near or distance prescription surrounding it.

INDICATIONS (USES)

OPERM™ F60 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

OPERM™ F60 rigid gas permeable contact lenses are indicated for the correction of refractive ametropia in non-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity.

OPERM™ F60 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, in otherwise non-diseased eyes.

CONTRAINDICATIONS (REASONS NOT TO USE)

OPERM™ F60 rigid gas permeable contact lenses are contraindicated by the presence of any of the following conditions:

- Acute or subacute inflammations of the anterior segment of the eye.
- Any eye disease, injury or abnormality, other than keratoconus, pellucid marginal degeneration, penetrating keratoplasty, LASIK or radial keratotomy surgery; that affects the cornea, conjunctive or eyelids.
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease, which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses and/or using contact lens solutions.
- Any active corneal infection (bacterial, fungal or viral).

WEARING SCHEDULE

THE EYE CARE PRACTITIONER SHOULD DETERMINE THE WEARING SCHEDULE.

Patients tend to over wear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

The maximum suggested wearing time for OPERM™ F60 rigid gas permeable contact lenses is:

DAILY WEAR (less than 24 hours while awake)

DAY	1	2	3	4	5	6	7	8	9	10-14	15 & After
SUGGESTED HOURS	3	4	5	6	7	8	9	10	11	12	All waking hours
HOURS WORN											

DO NOT SLEEP WHILE WEARING YOUR OPERM™ F60 RIGID GAS PERMEABLE CONTACT LENS. Studies have not been completed to show that the OPERM™ F60 (oxyflufocon A) rigid gas permeable contact lens is safe to wear during sleep. There is a tendency for some patients to overwear the lenses initially. It is important to adhere to the maximum wearing schedule above. Regular check-ups, as determined by the eye care practitioner, are extremely important.

GENERAL INFORMATION

Convention: Reference to OPERM™ F60 (oxyflufocon A) rigid gas permeable contact lenses

TINTS

OPERM™ F60 rigid gas permeable contact lenses are available in untinted (clear), tinted blue and green. The tinted lenses contain one or more of the following color additives: D&C Green No.6 and D&C Yellow No.10.

PRECAUTIONS – 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 clinical investigations of lenses, all refractive powers, design configurations or lens parameters available in the lens materials 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.
- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision.
- Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.

Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye care 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 for use with all lenses. Use only

recommended solutions.

- Do not heat the wetting/soaking solution and lenses.
- Keep away from extreme heat. Do not use heat or thermal lens care systems. Heat disinfection will damage the lens.
- Always use fresh unexpired lens care solution.

Always use a lens care system for your OPERM™ F60 (oxyflucon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens which has been recommended for use with fluorosilicone acrylate contact lenses.

- CONVENTIONAL HARD CONTACT LENS SOLUTIONS ARE NOT INDICATED FOR USE WITH THE OPERM™ F60 (oxyflucon A) RIGID GAS PERMEABLE SPHERICAL, ASPHERIC, TORIC AND BIFOCAL CONTACT LENS
- Always use FRESH rinsing and storage solutions.
- Always follow directions in the package Insert for the use of each contact lens solution.
- 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 a 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 wet table state. Follow the lens care directions for Care for a Dried out (Dehydrated) Lens if the lens surface does become dried out.

PRECAUTIONS - PATIENT

Follow the instructions below to prevent damage to your eyes or to your lenses.

- Before you leave your practitioners office be able to promptly remove your lens or have someone else be able to remove your lens for you.
- DO NOT WEAR YOUR OPERM™ F60 RIGID GAS PERMEABLE CONTACT LENSES WHILE SLEEPING UNLESS YOUR WEARING SCHEDULE IS INTENDED FOR EXTENDED WEAR.
- Always wash your hands with an additive free soap, rinse thoroughly and dry on a lint free towel before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams and deodorants come in contact with your lenses and if the lenses are contaminated by infectious or non-infectious debris.
- Always follow the recommended lens care system for your OPERM™ F60 lenses. Use the recommended lens care solutions and carefully follow the recommended directions.
- Always use FRESH rinsing, disinfecting and storage solutions.
- Do not use saliva, tap water or anything other than the recommended solutions to wet your lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn.
- Avoid using aerosol products such as hair spray while wearing your lenses. If hair sprays are used, keep your eyes closed until the spray has settled, otherwise, the lenses may be damaged.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Do not swim with your lenses in place.
- Never use tweezers or other tools to remove your lens from the lens container. Do not touch the lens with your fingernails.
- Always inform your doctor (general health care practitioner) that you wear contact lenses.
- Always consult your eye care practitioner before using any medicine in your eyes.
- Always inform your employer that you wear contact lenses. Some jobs may require the use of protective eye equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure continued health. CHECK WITH YOUR EYE CARE PRACTITIONER.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Do not heat the conditioning solution and lenses.
- The safety of these lenses with medications or contact lens solutions other than those recommended has not been established.
- If your lens sticks (stops moving) on the eye, follow the recommended directions for "Care for a Sticking Lens". The lens must move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, immediately consult your eye care practitioner.

CAUTION: Nonsterile. Clean and condition lenses prior to use.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

The following problems may occur.

- Eyes sting, burn or itch (irritation)
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye (foreign body, scratched area, abrasion)
- Excessive pain
- 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 you notice any of these adverse effects, **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 eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lenses; then reinsert it.
- If the problem continues, **IMMEDIATELY** remove your contact lens and consult your eye care practitioner.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. Immediately remove your lenses and seek professional identification of the problem and prompt treatment to avoid serious eye damage, including corneal scarring, opacification, blindness or loss of eye.

FITTING

Conventional methods of fitting rigid contact lenses apply to the OPERM™ F60 rigid gas permeable contact lens. For a description of fitting techniques, refer to the Fitting Guide for OPERM™ F60 Rigid Gas Permeable Contact Lenses. Copies of which are available from:

OPRI, Inc.
945 E. Juanita Avenue
Suite 112
Mesa, Arizona 85204-6619

CAUTION: Federal (US) law restricts this device to sale by, or on the order of, a licensed practitioner.

LENS CARE DIRECTIONS

Always wash your hands with an additive-free soap, rinse thoroughly and dry on a lint-free towel before you handle your contact lenses.

Never use tweezers or other tools to remove your lens from the lens container. Pour the lens into your hand.

OPERM™ F60 rigid gas permeable contact lenses must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. Leave the OPERM™ F60 rigid gas permeable contact lenses in a storage solution for a minimum of 4 hours or as indicated on the product label. To minimize lens warpage during

cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers. Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly as recommended by your lens care product manufacturer to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfection system as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber.

Tightly close the top of each chamber of the lens storage case.

To disinfect your lenses, leave them in the solution for at least 4 hours, or as indicated on the product label. Do not heat the conditioning solution and lenses.

Leave the lenses in the unopened storage case until you are ready to put them on your eyes.

Patients should fill their lens case with fresh solution every time they store their lenses, and never re-use solution. They should discard their solution immediately after their lenses have been removed from the lens case. They should not store their lenses in or rinse their lens case with tap water, bottled water or any non-sterile solution.

Patients should clean and rinse their lens case between uses as recommended by their eye care practitioner.

After you remove your lens from the lens case, empty and rinse your lens storage case with fresh, hot running tap water and allow it to air dry. When you next use the case, refill it with fresh storage solution.

OPERM™ F60 rigid gas permeable contact lenses should be disinfected using only a chemical (not heat) disinfection system.

Your eye care practitioner will recommend his/her preferred, FDA approved lens care solutions for the cleaning, disinfection, storage and lubrication of your OPERM™ F60 rigid gas permeable contact lenses.

Follow the instructions provided with each lens care solution. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless the eye care practitioner has determined that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply a few drops of a lubricating solution. Wait until the lens begins to move freely on your eye before removing it. If nonmovement of the lens continues, immediately consult your eye care practitioner.

HOW SUPPLIED

Always use a lens care system for your OPERM™ F60 (oxyflufocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens which has been recommended for use with fluorosilicone acrylate contact lenses

For information on material specifications contact:

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