



















# IMPORTANT NOTICE - INSTRUCTIONS FOR USE

EN

## CONTAINER LABEL DEFINITIONS

	Eye Care Professional
	Base Curve
	Diameter
	Power
	Cylinder Power
	Axis of cylinder
	Additional Power
	Non-sterile
	Batch code
	Caution
	Lens expiry date (year and month)
	Manufacturer
	Do not use if tamper-evident seal is damaged
	Product meets the standards set in the European Medical Device Directive
	Authorised representative in the European Community
	Importer
	Medical Device
	Consult instructions for use
3/12	3-month modality
12/12	12-month modality

This leaflet contains important **PRODUCT & SAFETY** information – please read carefully and retain for future reference.

Contact lenses should always be fitted by an Eye Care Professional (ECP) on non-diseased eyes.

It is essential that you follow your ECP's directions and all labelling instructions for proper use of your contact lenses.

Should the tamper-evident seal be broken, **DO NOT USE** the lens and return it to your ECP at the earliest opportunity.

## PRODUCT DESCRIPTION

Rigid Gas Permeable (RGP) contact lenses supplied in a wet state using a multi-purpose soaking solution and for single patient use and intended for daily wear.

## INDICATIONS FOR USE

### Vision Correction Spherical RGP contact lenses

Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**) in **phakic** or **aphakic** persons with up to approximately 0.75 D (dioptries) astigmatism that does not interfere with visual acuity.

### Toric RGP contact lenses

Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**) in **phakic** or **aphakic** persons with astigmatism over 0.75 DC (dioptric cylinder)

### Presbyopia

**Multifocal spherical RGP contact lenses**  
Indicated for the optical correction of distance and near vision in **phakic** or **aphakic** persons with up to 4.00D of add power and approximately up to 0.75D of astigmatism that does not interfere with visual acuity.

### Multifocal toric RGP contact lenses

Indicated for the optical correction of distance and near vision in **phakic** or **aphakic** persons with up to 4.00 D of add power with astigmatism over 0.75 DC.

### Irregular Cornea ALK, Woodward & McGuire RGP contact lenses

Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**) in **phakic** or **aphakic** persons with eyes who require management for keratoconus or other irregular corneas such as post refractive surgery, post graft surgery and trauma.

## MODALITY & DISCARD DATE

Lenses manufactured from RGP materials have a recommended maximum modality of 12 months wear. ECPs should instruct the patient as to the clinically preferred modality of these lenses. Wearing of lenses should be initiated within solution expiry date. Discard lenses 12 months after opening and wear.

## Expiry Date

Expiry date refers to the modality of the lenses from the day of manufacture.

The solution has an expiry of 1 month after the day of manufacture. The lenses must be cleaned using an RGP contact lens cleaning solution. Beyond the 30 days, ensure the lenses are cleaned and rinsed before insertion into the eye.

## MATERIALS

UltraVision RGP contact lenses are manufactured from the following materials.

OPTIMUM EXTRA BLUE & GREEN (roflucofon D 3 [100])  
OPTIMUM COMFORT BLUE, GREEN & GREY (roflucofon C 3 [65])  
CONTAPERM F2 MID Blue (focon 3[33])

## FREQUENT REPLACEMENT WEAR

When prescribed for Frequent Replacement Wear, the contact lenses are to be cleaned, rinsed and disinfected using commercially available multi-purpose or peroxide solutions each time they are removed from the eye and then stored using appropriate commercially available multi-purpose or peroxide contact lens solutions. Please refer to the instruction for use of the solution for further details on using the solution.

## LENS DISPOSAL

Contact lenses can be recycled through a dedicated recycling programme. Otherwise, they should be disposed of in general waste. Do not flush down the toilet or dispose of down the sink.

## CONTRAINDICATIONS

**DO NOT USE** the contact lens when any of the following conditions exist:

- Acute and sub-acute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the contact lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become **red** or **irritated**.

## PRECAUTIONS

**Do not allow non-sterile water (e.g. tap-water) to come into contact with the lens or lens cases due to increased risk of microbial infection.**

- Lenses should be stored for up to 30 days in the unopened lens case and solution until ready to wear. If they are stored for longer periods of time, disinfect again before wearing your lenses.
- Swimming or water sports should be performed only when water-tight goggles are worn to prevent contamination due to the increased risk of microbial infection.

# IMPORTANT NOTICE - INSTRUCTIONS FOR USE

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## Follow the guidance below for optimal contact lens performance

- Use only those solutions and products recommended by your Eye Care Professional (ECP) when cleaning your lenses and cases.
- Do not change the contact lens care system without consulting your ECP.
- Always maintain the recommended replacement schedule and return for the aftercare visits advised by your ECP.
- Should your lenses be prescribed on a frequent replacement basis, maintain the replacement schedule and always return for the after-care visits advised by your ECP.
- Certain medications may affect your ability to wear contact lenses. Advise your ECP of any new or changes to existing medications.
- Do not change to a different lens type or change lens parameters without consulting an ECP.
- In the event of redness of the eye, excessive lacrimation, pain or blurring of vision that is not attributable to contaminated lens surfaces, remove your lenses from the eyes and consult your ECP as soon as possible.
- Do not expose the lenses to hairsprays, cosmetics and aerosol sprays.
- Do not wear lenses during sleep unless your ECP advises to the contrary.
- If your lenses haven't been worn for a long period of time, follow the solution instructions before use.
- Multifocal contact lens wear may lead to nighttime glare and haloes or reduced contrast sensitivity. If you experience these symptoms, consult your ECP.
- RGP contact lenses do not protect your eyes from UV radiation. Therefore, it is recommended to use sunglasses that are verified as blocking UVA and UVB to give the best protection from the sun when wearing your lenses.
- Store at room temperature
- Ensure you distinguish between the right and the left lens.

## WARNING

**Remove contact lenses immediately if they come in contact with noxious vapour, e.g. chemical of hazardous substances or you are in an environment with hazardous fumes.**

In the event of redness of the eye, excessive lacrimation, pain or blurring of vision that is not attributable to contaminated lens surfaces, remove your lenses from the eyes and consult your ECP as soon as possible.

## INSERTION AND REMOVAL INSTRUCTIONS FOR PATIENTS

**ATTENTION TO PERSONAL HYGIENE IS VERY IMPORTANT. ENSURE THAT FINGER-NAILS ARE KEPT AS SHORT AS POSSIBLE.**

**Wash hands with warm water and soap, drying hands thoroughly before removing the lens from its container.**

### Lens Placement

Always start with the right lens. Inspect the lens, making sure it is clean and undamaged, then rinse with multi-purpose solution. Dry lenses are more susceptible to deposit accumulation, so handle them as little as possible and keep wet with multi-purpose solution. Extend the index and the middle fingers of the right hand and rest the contact lens in the depression between the two fingertips. Fill the lens completely with multi-purpose solution. Using the ring finger of the right hand, pull down the lower lid. Using the middle or index finger of the left hand, pull up the upper lid until the entire colour portion of the eye is exposed.

Look straight ahead with both eyes open and keep your head in a horizontal position. Slowly bring the lens towards the eye. When the wet surface of the lens touches the fluid layer of the eye, there will be an attraction of the lens to the surface of the eye. When the lens has settled in place, release the lids slowly and look down for several seconds. To insert the left lens, repeat the procedure.

### Lens Removal

Before removing your RGP lenses, have the following items available:

- Lens storage case
- Recommended cleaning solution
- Recommended multi-purpose solution

We recommend that a case without supporting prongs is used as these can distort the lens. The case should be cleaned regularly using a mild solution or detergent, rinsed thoroughly and allowed to air-dry before introducing a fresh supply of multi-purpose solution.

**Wash hands with warm water and soap, drying hands thoroughly before removing the lens from its container. Use a clean and bright environment to handle your contact lenses.**

Look down while gently pulling the upper lid up and above the contact lens edge with the index and middle fingers. At the same time, place the index finger of the other hand on the lower lid margin.

Slowly look up and gently push in and down with the two fingers on the upper lid, lifting the contact lens off the cornea. As the lens begins to lift off the eye, push the lower lid margin up and expel the lens from the eye. NOTE: It is important to have the fingers positioned properly on the lid margins.

RGP lenses can also be removed using a lens remover device. Gently apply the lens remover to the lower portion of the lens while looking straight ahead, or it may be applied to the upper portion of the lens while looking down. The lens is then gently lifted off the eye. (Do not place the lens remover directly on the centre of the lens).

When using a lens remover make certain that it is placed directly on the lens and not on the surface of the eye. Accidental application to the surface of the eye will be uncomfortable and could cause injury.

It is important that lenses are cleaned immediately after removal from the eye. See **Lens Care instructions**.

If you have any difficulty with these placement or removal techniques, your Eye Care Professional may recommend alternative procedures. Always follow your Eye Care Professional's recommendations.

## Lens Care

Your RGP lenses must be cleaned daily to remove surface deposits and prevent the formation of hard-to-remove residues.

Thoroughly clean the lens immediately after removal from the eye by applying several drops of cleaning solution to both lens surfaces, rubbing the lens between the fingers and palm with gentle pressure.

Rinse the lens thoroughly with multi-purpose solution, place it in the storage case, and cover it completely with multi-purpose solution. Close the lens storage case securely to prevent leakage. Repeat the procedure for the opposite lens.

## Re-Centering a Displaced Lens

If your lens becomes displaced onto the white of your eye, either during wear or during insertion or removal, you must locate the lens by pulling the lids apart as widely as possible while looking into a mirror.

Once the lens is located, place the index finger of one hand at the upper eyelid margin and the middle finger of the other hand at the margin of the lower lid. Look in the opposite direction of where the lens is located, and pull the lid margins up or down to get them beyond the lens edge. Gently place a lens removal device against the lens and lift it off the eye and re-insert the lens.

Under no circumstances should fingernails be used to pry the lens loose or move it back in place.

Alternative methods for re-centering may be suggested by your ECP.

Ensure your ECP notifies the manufacturer of the contact lens or authorised representative in the case of a serious incident.

Information specific to your contact lens(es) can be found on the contact lens packaging. This information contains the following:

- Contact lens prescription
- Trade name of the contact lens
- Material in which the lens is manufactured from
- Contact lens expiry date