IMPORTANT NOTICE – INSTRUCTIONS FOR USE

EN CE 1639 UK CA 0120

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

Should the tamper-evident seal be broken, DO NOT USE the lens and return it to your ECP at the earliest opportunity.
The information in this IFU refers to RGP contact lenses, which are intended for single-patient use and for daily wear. RGP contact lenses are packaged in flat-pack mailers in soaking solution containing:
Polyhexamethylene Biguanide (PHMB) 0.0005% & Disodium Edetate (EDTA) 0.01%.

The following information relating to your specific contact lens(es) can be found on the contact lens packaging:

- Right and left details
- Contact lens prescription
- Trade name of the contact lens design
- Material from which the lens is manufactured
- Contact lens expiry date

INDICATIONS AND INTENDED USE
These contact lenses are for prescribing and fitting by qualified ECPs in a clinical setting. Once prescribed, they are intended for daily wear by the patient in normal indoor and outdoor environments – **SEE PRECAUTIONS.**

Users should follow the recommended cleaning and disinfecting solutions and handle lenses in a clean, hygienic area with access to safe water or sterile solutions as advised.

Avoid use if environmental conditions prevent safe cleaning or wearing (e.g. severe dust exposure, caustic vapours, extreme temperatures).

PRODUCT DESCRIPTION
UltraVision RGP contact lenses are available in the following RGP materials:
OPTIMUM COMFORT (Blue, Green and Grey) (roflufocon C 3 (65))
OPTIMUM EXTRA (Blue and Green) (roflufocon D 3 [100])
CONTAPERM F2 MID (Blue) (focon 3 (33))

The following products for vision correction are available in ALL RGP Materials
Spheres
ALK, CLPL Kera, Eureka Asphere, McGuire, Rx, Topflex, Woodward, Xtralens Asphere
MF Spheres
SAM, SAM Xtralens
Torics
ALK, Rx, Xtralens
MF Toric
SAM, SAM Xtralens
All products are intended for daily wear and vision correction of patients of any age. Qualified ECPs can prescribe for specific age groups/eye conditions/wear schedules.
Vision Correction
Spheres/Aspheres
Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**) in **phakic** or **aphakic** people with low to moderate corneal astigmatism. Where significant residual astigmatism remains, or where corneal toricity prevents satisfactory fitting with a spherical lens, a toric RGP design may be required.
Torics
Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**) in **phakic** or **aphakic** persons with moderate or high astigmatism where satisfactory fitting cannot be achieved with a spherical lens.

Presbyopia
Multifocal Spheres
Indicated for the optical correction of distance and near vision in **phakic** or **aphakic** persons with up to 4.00 DS of add power and with low to moderate corneal astigmatism. Where significant residual astigmatism remains, or where corneal toricity prevents satisfactory fitting with a spherical lens, a toric RGP design may be required.
Multifocal Torics
Indicated for the optical correction of distance and near vision in **phakic** or **aphakic** persons with up to 4.00DS of add power with moderate or high astigmatism where satisfactory fitting cannot be achieved with a spherical lens.

Irregular Cornea
Spheres
ALK, CLPL Kera, McGuire, Woodward
Indicated for vision 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 with low to moderate corneal astigmatism. Where significant residual astigmatism remains, or where corneal toricity prevents satisfactory fitting with a spherical lens, a toric RGP design may be required.

Torics
ALK
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 with moderate or high astigmatism where satisfactory fitting cannot be achieved with a spherical lens.
MODALITY & DISCARD DATE
Unless otherwise indicated on the label, the following applies to ALL RGP lenses. 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.

New lenses
Wearing of **new** lenses should be initiated within the packaging solution expiry date, which is **1 month** after the date of manufacture. Beyond the 30 days, ensure the lenses are cleaned and rinsed before insertion into the eye. The lenses must be cleaned and soaked using solutions specifically sold for use with RGP contact lenses.
Discard lenses 12 months after opening and wear.

INSERTION AND REMOVAL INSTRUCTIONS FOR PATIENTS

ATTENTION TO PERSONAL HYGIENE IS VERY IMPORTANT. ENSURE THAT FINGERNAILS ARE KEPT AS SHORT AS POSSIBLE.

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

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 them 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.
Vision
This should be normal shortly after insertion, but if poor vision persists, check that the lenses are not in the wrong eyes.
Comfort If the lens is more uncomfortable than expected, it may be necessary to remove the lens for cleaning, rinsing and re-insertion.

Should discomfort persist, remove the lens and do not wear it again before consulting your ECP. Do not exceed the wearing time schedule advised by your ECP.

LENS REMOVAL
Wash hands with warm water and soap, drying them thoroughly before removing the lens from your eye(s).

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 removal 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.

Re-Centring 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 outer 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.

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PKG/040-11
Last time reviewed on:22/09/2026

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

LENS CARE
Your 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.

Compatible contact lens care products:
Boston Simplus Multi-action solution,
Boston Advance Cleaner, Ever Clean Plus
Peroxide system and Hycosan Extra eye drops

Contact lenses should be discarded after the recommended wearing period prescribed by the ECP or by the recommended discard date, whichever is sooner.

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

WEARING CONTACT LENSES SAFELY
Contact lenses are safe to wear in normal everyday conditions. However, there are certain circumstances and environmental conditions where you should not wear your lenses. Read the following information concerning **CONTRAINDICATIONS** & **PRECAUTIONS** carefully, as they explain when you should **NOT** wear contact lenses or need to take extra care. If in any doubt about the conditions in which you intend to wear your contact lenses, discuss this with your ECP.

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 exacerbated 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
Follow the guidance below to reduce the **risk of microbial infections.**

Do not expose contact lenses to water. Do not wear lenses while swimming, showering, bathing or participating in water sports. Contact with tap water, swimming-pool water, sea water or other non-sterile water may increase the risk of serious microbial eye infection.

- Never allow anyone else to wear your contact lenses. Sharing lenses greatly increases the chance of eye infections.
- Do not sleep in your lenses unless your ECP recommends it.
- Do not use saliva to wet your lenses
- Do not wear the lenses beyond the recommended wear time as advised by your ECP.
- Do not use **past** the expiry date.

REMOVE YOUR CONTACT LENSES IMMEDIATELY if you experience any of the following symptoms while wearing them. If symptoms persist after removal, consult your ECP as soon as possible to diagnose and manage any potentially serious eye condition and prevent further complications.

- Eye redness
- Excessive tearing (lacrimation)
- Irritation or discomfort
- Eye pain
- Blurred or reduced vision
- Sensitivity to light (photophobia)
- Signs of eye infection
- Swelling or inflammation (e.g., swollen eyelids, eye redness)
- Burning, grittiness, itchiness, or dryness
- Watery or abnormal eye discharge
- Sensation of a foreign body in the eye

FOLLOW THE GUIDANCE BELOW FOR OPTIMAL CONTACT LENS PERFORMANCE

- Use only those solutions and products recommended by your ECP when cleaning your lenses and cases.
- DO NOT freeze
- DO NOT change the contact lens care system without consulting your ECP.
- DO NOT exceed the wearing time schedule advised by your ECP.
- Always maintain the recommended replacement schedule and return for the aftercare visits advised by your ECP.
- Certain medications may affect your ability to wear contact lenses. Advise your ECP of any new medications or changes to existing ones.
- 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 contact lenses to hairsprays, cosmetics and aerosol sprays.
- Multifocal contact lens wear may lead to nighttime glare and haloes or reduced contrast sensitivity. If you experience these symptoms, consult your ECP.
- If your RGP contact lenses have not been worn for a long period of time, follow the solution instructions before use.
- Store at room temperature
- Ensure you distinguish between the right and left lens.

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

UV filters contained in contact lens materials do not fully protect your eyes from UV radiation and cannot protect the whole eye. It is recommended to use sunglasses that are verified as blocking UVA and UVB to give the best protection from the sun.

ADVERSE EVENTS
The users, patients, and healthcare professionals should report serious incidents related to a contact lens to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CONTAINER LABEL DEFINITIONS

ECP	Eye Care Professional
BCR	Base Curve
TD	Diameter
BVP	Power
Cyl	Cylinder Power
Axis	Axis of cylinder
ADD	Additional Power
FM	Flat Meridian
SM	Steep Meridian
R	Right
L	Left
NON STERILE	Non-sterile
LOT	Batch code
	Caution
	Date of manufacture (YYYY/MM/DD)
	Lens expiry date (year and month)
	Manufacturer
	Do not use if tamper-evident seal is damaged
	Single patient multiple use
CE 1639	Product complies with applicable European Regulations
EU REP	European Authorised representative
	Importer
MD	Medical Device
	Consult instructions for use
12/12	12-month modality
UKCA 0120	Product complies with applicable UK Regulations
UDI	Unique Device Identification

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