



IMPORTANT NOTICE - INSTRUCTIONS FOR USE

CONTAINER LABEL DEFINITIONS

	Eye Care Professional
	Base Curve
	Diameter
	Power
	Cylinder Power
	Axis of cylinder
	Device has been sterilised using steam
	Batch code
	Caution: Refer to instructions
	Lens expiry date (year and month)
	Manufacturer
	Do not use if tamper-evident seal is damaged
	For single use only
	Product meets the standards set in the European Medical Device Directive
	Authorised representative in the European Community

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).

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

The contents of contact lens packaging remain in a sterile condition until opened.

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

PRODUCT DESCRIPTION

Soft contact lenses supplied sterile for single patient use and intended for daily wear. Packaged in vials or blisters containing 0.9% borate buffered saline (blister packaging also contains Poloxamer 407NF).

INDICATIONS FOR USE

Vision Correction

Spherical soft 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 (dioptres) astigmatism that does not interfere with visual acuity.

Toric soft contact lenses

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

Presbyopia

Multifocal spherical soft contact lenses

Indicated for the optical correction of distance and near vision in **phakic** or **aphakic** persons with up to 4.00 dioptres (D) of add power and approximately up to 0.75DC of astigmatism that does not interfere with visual acuity.

Multifocal toric soft contact lenses

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

Irregular Cornea

KeraSoft® range of spherical soft contact lenses

Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**) in **phakic** or **aphakic** persons with non-diseased eyes who require management for keratoconus or other irregular corneas, such as post refractive surgery, post graft surgery and trauma with up to 0.75DC of astigmatism that does not interfere with visual acuity.

KeraSoft® range of toric soft contact lenses

Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**) in **phakic** or **aphakic** persons with non-diseased eyes who require management for keratoconus or other irregular corneas, such as post refractive surgery, post graft surgery and trauma with over 0.75DC of astigmatism that does not interfere with visual acuity.

Paediatric soft contact lenses

Indicated for the optical correction of refractive ametropia (**myopia** and **hyperopia**), up to 45.00 dioptres in **phakic** or **aphakic** persons with up to approximately 0.75 dioptres (D) of astigmatism that does not interfere with visual acuity.

Corneal Protection

Bandage soft contact lenses

For use as corneal protection during the healing process of conditions such as chronic epithelial defects, corneal ulcer, neurotropic keratitis, neuroparalytic keratitis, chemical burns and post-surgical epithelial defects.

For post-surgical conditions that include

LASIK, PRK, CXL, PK, PTK, Lamellar grafts, corneal flaps and additional corneal conditions.

Cosmetic & Prosthetic

Cosmetic spherical & toric soft contact lenses indicated for vision correction, presbyopia and irregular cornea for enhancing or changing the colour of the eyes using tints only.

Prosthetic spherical & toric soft contact lenses

indicated for vision correction, presbyopia and irregular cornea. This type of soft contact lens is designed for eyes which have sustained an injury or have a condition which causes unacceptable disfigurement. Prosthetic lenses are used to restore a normal appearance and are used for eye that have vision or are functionally blind. Lenses are specifically tinted to mask the natural appearance of the eye using opaquing methods over which tints are applied to match the appearance of a normal eye.

WARNING – CARE OF PROSTHETIC CONTACT LENSES

Multipurpose contact lens care solutions containing EDTA will adversely affect opaquing on prosthetic lenses and can cause fading. Only **peroxide based care solutions** should be used for storage and disinfection.

MODALITY & DISCARD DATE

Unless otherwise indicated on the label, the following applies to lenses from each material type:

Silicone Hydrogel

Soft contact lenses manufactured from silicone hydrogel materials have a recommended modality of up to 3 months wear. After opening, they should be discarded after the recommended modality period or on the expiry date, whichever comes first

Silicone hydrogel materials:

DEFINITIVE V3 74 Clear (efrofilcon A 5B (60) [74%])
DEFINITIVE V3 74 Blue UV (efrofilcon A 5B (60) [74%])





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Hydrogel

Soft contact lenses manufactured from hydrogel materials listed below have a recommended modality of up to 12 months wear. They should be discarded 12 months after opening or on the expiry date, whichever comes first.

Hydrogel materials:

- CONTAFLEX 38 Clear UV (filcon 1 (8) [38%] Class II UV Protection)
- CONTAFLEX 55 Blue (methafilcon A 4 (19) [55%])
- CONTAFLEX 58 Clear (filcon 2 (21) [58%])
- CONTAFLEX GM3 58 Clear (acofilcon A2 (26) [58%])
- CONTAFLEX 67 Clear (filcon 2 (30) [67%])
- CONTAFLEX 77 Clear (filcon 2 (45) [77%])
- BENZ-G3X 49 Blue (hioxifilcon B 1 (15) [49%])
- VISTA 72 Clear (filcon 2 (33) [73%])

FREQUENT REPLACEMENT WEAR

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

Contact lenses should be discarded after the recommended wearing period prescribed by the ECP or by the recommended discard date, whichever is sooner. (see **DISCARD DATE**)

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**.

NOTE: Some of these conditions may require the use of a bandage lens when prescribed by an ECP.

PRECAUTIONS

Follow the guidance below to reduce the risk of microbial infections

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.

- Swimming or water sports should be performed only when water-tight goggles are worn to prevent contamination due to increased risk of microbial infection.
- Do not shower or bathe whilst wearing soft contact lenses.

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 change the contact lens care system without consulting your ECP.
- If your lenses have not been worn for a long period of time, follow the solution instructions before use.
- 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 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 contact lenses to hair-sprays, cosmetics and aerosol sprays.
- Do not sleep in your contact lenses unless your ECP recommends it.
- 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 soft contact lenses have not been worn for a long period of time, follow the solution instructions before use.

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.

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.

INSERTION AND REMOVAL INSTRUCTIONS FOR PATIENTS

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

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

- Remove the lens from its container, ensure that it is not inside out and place the lens on the tip of the forefinger. Look into a mirror and, with the middle finger of the same hand, draw down the lower lid.
- With the middle finger of the free hand, pull the upper lid upwards and place the lens gently over the visible iris. Release the lids slowly.

LENS REMOVAL

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

Applying downward pressure on the lower lid whilst looking up will help move the lens downwards. Then gently ease the lens onto the 'white' of the eye using the fingertip. The lens can then be pinched off the eye using the thumb and forefinger.

Following removal, clean and store your contact lenses in accordance with the instructions provided by your ECP.

VISION

This should be normal shortly after insertion but, if poor vision persists check that the lenses are not inside out or in the wrong eyes.

COMFORT

If the lens is uncomfortable, it may be necessary to remove the lens for cleaning, rinsing and re-insertion. Again, if the lens is inside out, discomfort may be felt and the lens will require removal, reversal and cleaning prior to 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.

