

# IMPORTANT NOTICE - INSTRUCTIONS FOR USE

This leaflet contains important information – Please read carefully and retain for future reference. Contact lenses should always be fitted by an Eye Care Professional.

It is essential that you follow your Eye Care Professional's direction and all labelling instructions for proper use of your contact lenses.

All containers maintain the lens in a STERILE condition until opened. Should the seal be broken, DO NOT use the lens and return to your Eye Care Professional 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**

### **Spherical soft contact lenses**

Indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with up to approximately 0.50 dioptres (D) astigmatism that does not interfere with visual acuity.

### **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 0.75D of 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 0.50 DC.

### **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.

### **KeraSoft 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 with up to approximately 1.50 dioptres (D) of astigmatism that does not interfere with visual acuity.

KeraSoft toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with astigmatism over 1.50 DC.

### **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.

### **Aphakic soft contact lenses**

Indicated for the optical correction of refractive ametropia for persons who have cataract extraction without subsequent intraocular lens implantation (i.e. have the condition aphakia).

NOTE: Supplemental spectacles may be required for aphakic persons in some conditions to provide near vision or to compensate for uncorrected refractive astigmatism.

### **High Myopia soft contact lenses**

Indicated for the optical correction of significant myopia in phakic or aphakic with up to approximately 1.50 dioptres (D) 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 1.50 dioptres (D) of astigmatism that does not interfere with visual acuity.

### **Modality**

Lenses manufactured from SiH 74% Blue/UV Filcon V3 material have a recommended modality of 3 months wear. Lenses manufactured from hydrogel\* materials have a recommended modality of up to 12 months. Eye Care Professionals should instruct the patient as to the clinically preferred modality of these lenses.

\*Hydrogel materials include: GM3 58% Filcon II 1, SELECT 49% H-Filcon B11, 38% UV Filcon I 1, 58% Filcon II 2, 67% Filcon II 2, 77% Filcon II 3, 72% Filcon II 2, 55% Filcon IV 1.

### **Frequent Replacement/Planned Replacement Wear**

When prescribed for Frequent/Planned Replacement Wear, the lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the Eye Care Professional. The lens may be disinfected using multi-purpose or peroxide contact lens solutions.

### **Discard Date**

Discard lenses manufactured from SiH 74% Blue/UV Filcon V3 material 3 months after opening. Discard lenses manufactured from Hydrogel material 12 months after opening or when the expiry date is reached, whichever is sooner. Bandage lenses are intended for single use only and should be discarded after use.

### **Contraindications**

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

- Acute and subacute 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 Eye Care Professional.



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## Precautions

- Do not allow non-sterile water (i.e. 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.
- Use only those solutions and products recommended by your Eye Care Professional when cleaning your lenses and cases.
- Do not change the contact lens care system without consulting your Eye Care Professional.
- Do not exceed the wearing time schedule advised by your Eye Care Professional.
- Should your lenses be prescribed on a frequent replacement basis, maintain the replacement schedule and always return for the aftercare visits advised by your Eye Care Professional.
- Certain medications may affect your ability to wear contact lenses. Advise your Eye Care Professional of any new or changes to existing medications.
- Do not change to a different lens type or change lens parameters without consulting an Eye Care Professional.
- 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 Eye Care Professional as soon as possible.
- Do not expose the lenses to hairsprays, cosmetics and aerosol sprays.
- Do not wear lenses during sleep unless your Eye Care Professional advises to the contrary.
- Contact lenses should be removed immediately after contact with noxious vapour, e.g. chemical of hazardous substances or hazardous environment with ocular impact not included on the IFU.

- If your lenses haven't been worn for a long period of time, follow the solution instructions before use.
- UV filters contained in contact lens materials do not fully protect your eyes from UV radiation and cannot protect the whole eye. Therefore, it is recommended to use sunglasses that are verified as blocking UVA and UVB to give the best protection from the sun.

## Insertion instructions for patients

### Prior to lens insertion

It is recommended that lenses are rinsed with a multi-purpose solution after initially removing from packaging and before inserting into the eye.

Wash and dry hands before removing the lens from its container. ATTENTION TO PERSONAL HYGIENE IS VERY IMPORTANT. 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.

### 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 EYE CARE PROFESSIONAL.

### Lens removal














Wash and dry hands before the removal of your contact lenses.

Downward pressure on the lower lid whilst looking up will tend to move the lens downwards and it is then easy to 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.

ENSURE THAT FINGERNAILS ARE KEPT AS SHORT AS POSSIBLE.

Following removal, clean and store in accordance with the instructions provided by your Eye Care Professional.

## Container label definitions

	Base Curve
	Diameter
	Power
	Cylinder Power
	Axis of cylinder
	Device has been sterilized using steam
	Batch Code
	Caution: Refer to instructions
	Lens expiry date (year and month)
	Manufacturer
	Do not use if package is damaged
	For single use only
	Product meets the standards set in the European Medical Device Directive

