

FreshKon[®] Alluring Eyes • FreshKon[®] Colors Fusion • FreshKon[®] Mosaic

A Guide to Trouble-Free Contact Lens Wear (Instructions for Use)

Consult an Eye Care Professional for suitability of wear

www.freshkon.com

Contents

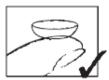
Sterile one day disposable daily wear soft contact lenses, 42% etafilcon A, 58% water, immersed in 0.9% buffered saline.

Indications for Use (Intended Purpose)

Is applied directly to the cornea, and is designed for daily wear to enhance the color and/or the size and/or the definition of the natural iris and/or for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00 diopter (D) or less of astigmatism (Except plano lens). It also helps protect against transmission of harmful UV radiation to the cornea and into the eye. Eye Care Professionals may prescribe the lens for single-use daily disposable wear.

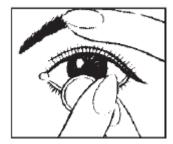
Lens Insertion

- 1. Wash your hands thoroughly with soap and dry them with a lint free towel.
- 2. Pour the lens into your clean palm. If the lens sticks to the bottom of the blister, gently move it back and forth with the base of your finger until it slides freely instead of using tweezers or other tools.
- 3. Place the lens on the tip of your index finger. Make sure the lens is in a bowl shape and correctly oriented.

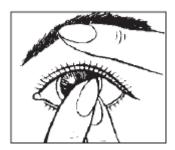




4. Hold up your upper eyelid firmly with one finger of your other hand.



5. While holding down the lower eyelid with one finger of your applying hand, carefully place the contact lens on your cornea.



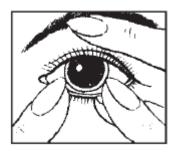
6. Slowly release upper eyelid and gently close your eyes.

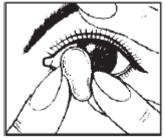


7. Repeat the same procedure for the other eye.

Lens Removal

- 1. Wash your hands thoroughly with soap and dry them with a lint free towel.
- 2. Check to ensure lenses are on your cornea.
- 3. Hold down lower eyelid with your middle finger.
- 4. Use forefinger to slide lens to lower part of eye.
- 5. Gently pinch the bottom edge of the lens with the pad of your index finger and thumb to remove lens.

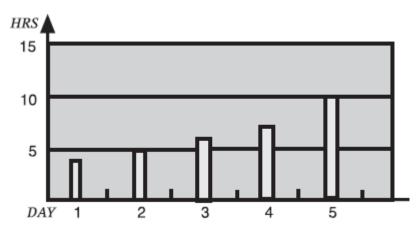




6. Repeat the same procedure for the other eye.

Schedule for Daily Wear/ Recommended Replacement Schedule/ Follow-up Visits

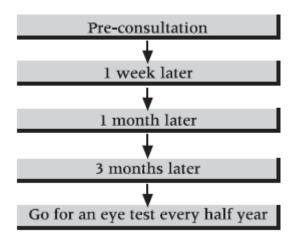
Schedule for Daily Wear



Note: You may notice a slight blur to the side when first wearing cosmetic contact lenses. This is normal for cosmetic contact lenses. Vision will improve after the wearer undergoes an adaptation period.

- 1. Never wear your lenses beyond the period recommended by your Eye Care Professional.
- 2. These lenses are single-use devices, and once removed, they are to be discarded. They are not indicated for overnight wear and you should not wear them while sleeping. They are not to be cleaned and disinfected. Clinical studies have shown that the risk of serious adverse reactions is increased when these lenses are worn overnight and being reused. You should always carry a spare pair of lenses with you.
- 3. The lenses are meant for daily wear.

Follow-up visit



Contraindications/ Warnings/ Precautions/ Adverse Reactions

- 1. The safety and effectiveness of contact lens depends on proper use, eye infection with possible permanent damage to vision, can result from the failure to strictly follow instructions recommended in IFU.
- 2. Do not use the contact lens if any of the following conditions exist: (a) Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids (b) Any active corneal infection (bacterial, fungal, protozoal, or viral) (c) If eyes becomes red or irritated.
- 3. In the event of an adverse reaction to the wearing of the contact lens, including discomfort to the eye, red eye, excessive tearing and blurred vision and/or unusual eye secretions, the user should immediately remove the contact lens and consult an eye care professional before resuming use. It is also recommended that you see your eye care professional routinely, as directed in IFU.
- 4. Eye care professional should be consulted regarding the use of the contact lens in certain atmospheric or environmental conditions that can cause irritation to the eyes.
- 5. Avoid all harmful or irritating vapors and fumes while wearing lenses.
- 6. Ask your Eye Care Professional about wearing lenses during sporting activities eg. swimming.
- 7. Put on your lenses before putting on makeup. Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on your lenses.
- 8. Do not use if the sterile package is opened or damaged.
- 9. If the lens appears damaged while placing on the tip of your index finger, do not use it.
- 10. Do not share your contact lenses with others.
- 11. Do not attempt to wash or clean your lenses. Always wear a fresh pair of lenses.
- 12. Always consult your Eye Care Professional on the suitability of lenses used and parameters.
- 13. The recommended storage temperature of contact lenses is below 27 °C to ensure the product shelf life is valid.

Symbol Reference Guide on Packaging and Label

| ••• | Manufacturer | C € 1639 | Quality System Certification Symbol |
|---------|------------------------------------|-----------------|--|
| EXP∑ | Use- by date | EC REP | Authorized representative in the European Community |
| LOT | Batch code | Rx only | CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed eye care professional |
| STERILE | Sterilized using steam or dry heat | PWR | Diopter (Lens Power) |
| 2 | Do not re-use | BC | Base Curve |
| i | Consult instruction for use | DIA | Diameter |



Rx only

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EC **REP**

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These products are certified as medical devices in the European Union under the Medical Device Directive 93/42/EEC by SGS CE1639, exclusively for the indication(s) of optical correction of refractive ametropia (myopia and hyperopia). Other non-medical uses ascribed to these devices are not within the scope of CE certification, and users should be aware product performance and/or safety has not been evaluated by SGS for those purposes.