

This Patient Instruction is for Daily Disposable Soft Contact Lens.

1. Product Information

Product Name : I-Lux Innova Soft Contact Lens

Type: Single use

Models : **Daily Disposable** Soft Contact Lens with UV blocker

Models Code: A91

Material: Etafilcon A

Water Content: 58%

Visible Light Transmission: >93%

UV Transmittance: UV(A) <30%; UV(B) < 5%. (UVA / UVB Class II)

2. Important Information

Please read carefully and keep this information for future use.

The **Daily Disposable** Soft Contact Lens is daily wearing single use contact lenses. Once removed, they are to be discarded. They are not intended to be cleaned and disinfected. You should always carry a spare pair of lenses or glasses with them.

Base on the use of safety, the manufacturer has performed risk management on every manufacturing process and the clinical evaluation of the product. All results reveal that the product has its performance and safety. Use directions and notices that are illustrated in this document in detail. As a result, hazards could be avoided by following the instructions.

The safe and effectiveness of contact lenses depend on proper use.

3. Lens Parameters Available

Diameter: 13.2 ~ 14.8 mm

Base Curve: 8.0 ~ 9.2 mm

4. Indications (Use)

The product is indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopia or hyperopia and may exhibited refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The product is supplied sterile in sealed blister packs containing sterile buffered isotonic saline solution with Moisturizing ingredients.

5. Contraindications (Reasons Not To Use)

DO NOT USE this 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), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Any active corneal infection (bacterial, fungal, protozoal or viral).
- If eyes become red or irritated.

6. Warnings

PROBLEMS WITH CONTACT LENSES COULD RESULT IN SERIOUS INJURY TO THE EYE.

- Problems with contact lenses could result in serious injury to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical studies have shown that the risk of serious adverse reactions is increased when daily wear lenses are worn overnight.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomforts, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care practitioner.
- UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed.
- NOTE: Long term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-Blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-Blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

YOU SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

Please note there are additional risks if you reuse of contact lens:

- ✧ The chance of infection may increase.
- ✧ You may experience blurred vision due to inappropriate cleaning of lens surface.
- ✧ Lenses may become physically compromised by repeatedly removing and re-inserting lenses.

7. Precautions

- The lenses are prescribed for **daily disposable**, and are to be disposed of once they are removed from the patient's eye. It is important that patients be instructed to always have available a pair of replacement lenses. In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant gets on the lens or the lens becomes dehydrated, the lens should be removed and replaced with a replacement lens.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If the non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner. Do not attempt to remove the lens, except on the instructions of the eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-based products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Information Booklet and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during water activities and other sports.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always discard disposable lenses after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

8. Adverse Effects

The following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when the lens was first placed on the eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses.**
- **If the discomfort or problem stops, then look closely at the lens. If the lens is in some way damaged, do not put the lens back on the eye, and replaced with a new lens.**

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. The patient should keep lens off the eye and Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

9. Fitting procedure

• Prepare wearing the lens	
	(1) Clean the hand before opening the blister. (Wash the hand and dry the hand.)
	(2) Take the lens out of the blister using hands or the clip (avoid finger nails and sharp objects).
 	(3) Put the lens on the finger. (4) Check the back curve side upward and the other issue.

	(5) Place the middle finger of the same hand and pull down the lower lid. (6) Use the forefinger or middle finger of the other hand to lift the upper lid.
Take out the lens after using	
	(1) Clean the hand before taking out the lens.
	(2) Use one finger to pull the upper lid and use the thumb and index finger of the other hand to take out the lens from the eye.
	(3) Discard the lens in the trash can when take out.

10. Wearing Schedule

The wearing and replacement schedules should be determined by the eye care practitioner. Patients tend to overwear the lenses initially. The eye care practitioner should emphasize the importance of adhering to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

The recommended maximum wearing schedule is:

Maximum Wearing Time	
Day	Wear Time (Hours)
1 st	4
2 nd	6
3 rd	8
4 th	10
5 th	12
6 th and above	All waking hours*

* The wearing schedule should be determined by the eye care practitioner. Studies have not been performed to support safety for extended wear (greater than 24 hours) of this lens.

* It is recommended to wear it daily to avoid more than 12 hours.

11. Emergencies

The patient should be informed that If chemicals of any kind (household products, gardening

solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

12. Symbol Key

The following symbols may appear on the label or carton:

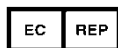
Symbol	Definition
	Manufacturer
	Authorized Representative in Switzerland
	Authorized representative in the European Community / European Union
	CE quality system certification symbol
	Use By Date (Expiration Date)
	Batch code
	Country of manufacture
	Sterilized using steam or dry heat
	Do not use if package is damaged and consult instructions for use
	Single sterile barrier system
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution, consult accompanying documents
	Medical device
	Unique Device Identifier

DIA	Diameter
BC	Base Curve
P	Diopter (Lens Power)
	UV Blocking
	Importer
	Distributor



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