

SEED AS-LUNA

April 2020 (version 4)

Revised in May 2017 (version 3) (revision based on the new description guideline)

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[Warnings]

1. Wearing contact lenses ("lenses" hereinafter) may cause corneal ulcers, keratitis (including infectious keratitis), corneal infiltration, corneal epithelial disorders such as corneal erosion, corneal edema, conjunctivitis (including giant papillary conjunctivitis), iritis, and corneal neovascularization, and accelerate loss of corneal endothelial cells. If left untreated, eye disorders due to use of lenses may lead to blindness.
2. To prevent eye disorders as listed above, observe the following instructions when using the lenses.

(1) Keep to the wear schedule.

The wear schedule differs for each individual. Follow the wear schedule given by your eye doctor.

In extended wear, please observe the contents in the Extended Wear Approval Document and Management Booklet.

(2) Use the lenses according to the procedures given.

Improper use of the lenses and lens care products may lead to eye disorders.

Keep the lenses and lens care products clean (particularly the lens case). Handle carefully and use only as instructed.

(3) Get regular contact lens checkups.

Note that eye disorders and lens damage may occur without subjective symptoms.

Get regular contact lens checkups as instructed by your eye doctor even if you experience no problems.

(4) Consult your eye doctor immediately if you experience any problems or notice anything unusual.

Confirm that your eyes are free of unusual redness or discharge before inserting the lenses. No discomfort or irritation should occur during use. If you experience discomfort or problems, consult your eye doctor.

(5) Never use torn or otherwise damaged lenses.

Always inspect your lenses to confirm they are free of tears and other damage. If you experience persistent symptoms that may be due to lens damage, consult your eye doctor.

[Contraindications]

1. Contraindications (patients): Do not use the lenses if any of the followings applies:

Acute or subacute inflammation in the anterior ocular segment

Ocular infection

Uveitis

Reduced corneal sensitivity

Dry eye or lacrimal apparatus disease that affects use of the lenses

Abnormality in the eyelids

Allergic disease affecting lens use

Living or working in dry environments

Living or working in an environment where dust or chemicals are likely to enter the eye

Unable to follow the recommendations of your eye doctor

Unable to use contact lenses properly

Unable to get regular checkups

Unable to adhere to the hygiene routine required to wear contact lenses

2. Method for use

Do not wear someone else's contact lenses or give your contact lenses to someone else.

[Form, structure and principle]

1. Composition of the lenses

- Monomer components: methacrylate compounds with fluorine/methacrylate compounds with silicon

- Oxygen permeability coefficient:

$(156 \pm 31) \times 10^{-11} \text{ (cm}^2\text{/sec)} \cdot \text{(mLO}_2\text{/(mL} \cdot \text{mmHg))} \cdot \text{(gravitational system of unit)}$

$(117 \pm 23) \times 10^{-11} \text{ (cm}^2\text{/sec)} \cdot \text{(mLO}_2\text{/(mL} \cdot \text{hPa) (SI units)}$

- Colorant: Phthalocyanine colorant

2. Storage solution

Major ingredients of the storage solution: Anionic surfactant and buffer (borate)

3. Principle: Vision is corrected by the refractive power applied to the contact lenses and tear fluid between the lens and cornea.

[Purpose of use or effect]

To correct vision

[Method of use]

You must use the lenses according to the instruction of your eye doctor.

- Daily wear or extended wear (up to 7 days)

<Precautions for use>

1. Inserting/removing the lenses

1) Lens handling precautions

- (1) Keep your fingernails short and smooth so as not to damage the lenses.
- (2) Wash your hands with soap and rinse off any soap well before touching the lenses.
- (3) Do not dig your nail into the lenses or touch your eyes directly while inserting or removing the lenses.

2) Removing the lenses from the packaging

- (1) At the first opening, dispose of all of the storage solution in the bottle. Thoroughly wash both the bottle and lenses with multi-purpose solution or sterile saline before starting use. (Mixing the storage solution and other care products may make the solution thicker or produce sediment. This may also occur depending on storage conditions even without mixing.)
- (2) Inspect the lens to determine which lens is for the right eye and which lens is for the left eye. Check to determine the inside and outside of the lenses.

3) Inserting the lens

- (1) Place the lens on the index finger of your dominant hand.
- (2) Pull down your lower eyelid with the middle finger of the same hand and pull up your top eyelid with the index finger of your other hand.
- (3) Open the eye wide while looking into the mirror and place the lens on the cornea.
- (4) When you have placed the lens on the cornea, slowly release your fingers and close the eye gently to stabilize the lens position.
- (5) Cover the opposite eye with your hand to check your sight.
- (6) Follow the same procedure to insert the lens in your other eye.

4) Removing the lens

- (1) Check the position of the lens in the mirror to confirm that the lens is on the cornea.
- (2) Place the palm opposite to the lens to be removed, below the eye. Pull the tale of the eye outwards towards the ear and slightly upward with the index finger of the same hand, and blink gently. The lens is trapped by the upper and lower eyelid and falls. Catch the lens in your hand.

2. Wear schedule: The wear schedule may differ from person to person. Follow the instructions of your eye doctor.

1) Daily wear

(1) First use

- Prolong the wearing time gradually to become accustomed to them, referring to the following example.

Day 1: Up to 8 hours	Note) You must remove the lenses before sleeping.			
Day 2: Up to 10 hours				
Day 3: Up to 12 hours				
Day 4: Up to 14 hours				
Day 5: Up to 16 hours				
Day 6: All waking hours (starting after waking up until going to bed)				

(2) The extent of soiling differs according to the individual. If your lenses soil easily, your tear volume is low, you are allergic or have oily skin or you practice extended wear, use the special scrubbing cleaner Gel Clean or protein remover according to the instructions of your eye doctor.

*Note that you cannot use strong chlorine cleaners.

(3) You must read the detailed lens care procedures in Instructions for Use (Package Insert and Labeling).

4. Lens case management

1) Replace the lens case with a new lens case at periodic intervals.

2) After using the lens case, dispose of the storage solution in the case, thoroughly wash the lens case, and allow to dry.

5. Regular checkups

You must get regular contact lens checkups as instructed by your eye doctor.

1) Daily wear

One week, one month, three months, and then every three months after the first day of use

2) Extended wear

The first day of extended wear, the next day, one week, one or two weeks after and one month after the first wear and then monthly

[Precautions]

1. Important basic precautions

1) Carefully read these Instructions for Use before using your contact lenses. Keep the Instructions in a safe place for future reference.

2) Consult your eye doctor if you have an allergic disease. Allergic conditions may increase the likelihood of adverse events.

3) If you feel any abnormality immediately after putting on the lenses or while wearing the lenses, immediately remove the lenses and see your eye doctor.

2. Problems/adverse events

1) Important problems/adverse events

(1) Important adverse events

Corneal ulcers, corneal abscess or corneal perforation may develop if you do not observe the appropriate method of using lenses or if external stimuli, allergy, viral/bacterial/mycotic infection or Acanthamoeba is present. If you recognize any abnormality, stop using them and see your eye doctor.

2) Other problems/adverse events

The following problems and adverse events may occur:

(1) Problems

Lens: foreign particles, clouding, tearing, scratches, deformation, discoloration, staining, everted (inside out)

(2) Adverse events

Corneal infiltration, corneal epithelial abrasion, corneal erosion, bacterial keratitis, corneal herpes, corneal edema, keratitis (including infectious keratitis), corneal epithelial staining (including superficial punctate keratopathy), corneal epithelial disorders including epithelial splitting, heat sensation of eye, corneal neovascularization, loss of corneal endothelial cells, iritis, pigment slide, bacterial conjunctivitis, allergic conjunctivitis, conjunctivitis (including infectious conjunctivitis and giant papillary conjunctivitis), subconjunctival hemorrhage, blepharitis, hordeolum, meibomitis, chalazion, ptosis, poor vision, eye pain, foreign body sensation, discomfort while wearing, sensation of pressure, hyper-eyeblink, abnormal feeling of the eyes (strange feeling, tiredness, irritation), abnormal vision (darkness, reduced vision, blurred vision, flicker), unusual redness of the eyes, unusual eye discharge, continuous lacrimation, eye itching, eye-smarting, dry eye, feeling of dryness, asthenopia (including accommodative asthenopia), headache, poor mood, dizziness, difficulty in inserting and removing the lenses, and sticking

<Symptoms and countermeasures]

- Do not use forcibly if your eyes are not in good condition or you are unwell.
- Try the following countermeasures if you experience any of the following symptoms while using the lenses. If symptoms persist, consult your eye doctor immediately.

Symptoms	Countermeasures
Foreign body sensation, pain, itching, clouding, unusual eye discharge, and unusual redness of the eyes	<ul style="list-style-type: none">• Check the lenses. Replace with new lenses if they appear torn or otherwise damaged.• If the lens appears dirty, gently rub and rinse the lens.• If the symptoms occurred after extended periods of wear, try wearing them for shorter periods.
Unstable visual acuity, difficulty in seeing, and eye strain	<ul style="list-style-type: none">• Check which lens is for the left eye, which lens is for right, and inside/outside of the lenses and reinsert the lenses correctly.• If the symptoms occurred after extended periods of wear, try wearing them for shorter periods.
Feeling of dryness	<ul style="list-style-type: none">• Blink several times to produce more tears.

3. Use by elderly persons

- 1) For use by elderly persons or persons having difficulty in inserting, removing and lens care by themselves, consult an eye doctor and follow the doctor's instructions.

4. Use by pregnant, parturient and breastfeeding women and children

- 1) If you use medication or eye drops or if you are pregnant or have just given birth, consult your eye doctor. Your condition may affect lens use.
- 2) A child should use the lenses under supervision of parents.

5. Other precautions

- 1) Take spare lenses and glasses with you in case you lose or have to stop using the lenses.
- 2) Put on make-up after putting on the lenses and remove the make-up after removing the lenses.
- 3) Do not allow cosmetics to come into contact with the lenses.
- 4) Basically, avoid use of eye drops while wearing the lenses. Some ingredients in eye drops may affect the lens quality. If you need eye drops use while using the lenses, consult your eye doctor.
- 5) Remove the lenses before swimming.
- 6) If you use the lenses in a foreign country, carry the lens care products necessary with you.
- 7) If you are abroad for extended periods, get regular checkups at a local medical institution.

[Storage and expiration period]

1. Storage

- 1) Storage of unopened lens packages

Store at room temperature avoiding direct sunlight.

2. Expiration period

- 1) Start use within the expiration period indicated.

[The expiration period indicated is certified by SEED (based on data by SEED)]

(Example: If marked "202008", start use by August 2020.)

[Maintenance]

1. Lens care: See [Precautions for use] 3. Lens care.
2. At the regular checkup, consult your eye doctor to confirm you can continue wearing the lenses.

[Name of Marketing Authorization Holder and Manufacturer]

[Marketing Authorization Holder]

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