

# INSTRUCTIONS FOR USE

## Breath-O Correct®

**Please read carefully before use and keep this information for future use.**

### [Description]

#### 1. Principles

Corneal topography is reshaped by direct wear of the contact lens on the anterior segment of the eye. After removal, unaided vision is improved.

#### 2. Composition

Fluoride-containing methacrylate compound  
Silicon-containing methacrylate compound

### [Intended use]

The Breath-O Correct is indicated for overnight wear for myopia and myopic astigmatism. It reshapes the cornea, and provides improved vision after removing lenses.

### [Indications]

Vision correction for myopia or myopic astigmatism (Spherical power is between -1.00 D and -4.00 D and cylindrical power is 1/2 or less of the spherical power. However, in case of inverse astigmatism, the cylindrical power is 1/2 or less of the myopic power, and the astigmatic power is -0.75 D or less).

### [Instructions of use (Operation procedures, usage, etc.)]

Explain the characteristics of the cornea-reshaping contact lens to the patient so that he/she can understand the characteristics thoroughly, including the necessity of a long time (period) to attain the intended unaided vision.

#### 1. Prescription procedures

Prescription procedures should follow the outline, as mentioned below.

- (1) Interview
- (2) Anterior eye segment examination and funduscopy
- (3) Corneal topography measurement
- (4) Objective refraction test
- (5) Corneal endothelial cell measurement (at least 2,000/ mm<sup>2</sup>)
- (6) Tonometry
- (7) Visual acuity test
- (8) Tear test (Schirmer's test, at least 5mm in 5 minutes)
- (9) Measurement of a pupil diameter
- (10) Selection of trial lenses
- (11) Fitting test
- (12) Confirmation of the suitability of prescription
- (13) Additional correction
- (14) Decision of lens specification
- (15) Giving instructions to the patient (Lens insertion and removal, etc.)

#### 2. Confirmation of the suitability of prescription and criteria for prescription

- (1) The lens curve should be selected taking into account the shape of the cornea and values of the periphery measured by corneal topography.
- (2) The Eye Care Practitioner should evaluate the fitting condition after 15 minutes of lens wear to confirm the suitability.
  - The fluorescein pattern should be the proper doughnut pattern.
  - Lens movement at eye blinking should be good.
  - The lens should be positioned in the center of the cornea.
  - Wearing feeling should be comfortable.
  - Lens power should be deliberately selected taking into account the over refractive index.

#### 3. Insertion and removal by the Eye Care Practitioner

Cut the fingernails short and round before handling the lenses. Always wash the hands and fingers with soap, and rinse off completely.

#### [Lens insertion procedures]

- (1) Take out a lens from the lens case, pour lens care products, rub it, and wash out by lens care products. Use the same procedure even if it is unused lenses.
- (2) Place the lens on the index finger.
- (3) Put a few drops of artificial tear eye-drops or a similar substance on the concave side of the lens. Be careful not to get air bubble at that time.
- (4) Ask the patient to look downward, pull the lower eyelid down with the middle finger of the same hand as that of the index finger on which the lens is placed, and lift the upper lid with the index finger of the other hand.
- (5) Gently place the lens on the cornea.
- (6) After checking that the lens is placed on the cornea, slowly release the fingers from the eyelids and ask the patient to gaze straight ahead. Confirm whether the lens is correctly placed on the cornea and that the patient has no pain.
- (7) Use the same procedure when inserting the other lens.
- (8) DO NOT USE SALIVA, TAP WATER AND BOTTLED WATER.

#### [Lens removal procedures]

- (1) Apply the artificial tear eye-drops or a similar substance to the eye, and confirm that the lens become movable on the cornea.
- (2) Ask the patient to look straight ahead, and gently press the upper eyelid with the finger of one hand.
- (3) Fix the lower eyelid using the finger of the other hand so that the lens does not slip under the lower eyelid, and remove the lens hooking the edge of the lens with the upper eyelid.
- (4) Rub the lens by lens care products, wash out by lens care products, and place to the lens case with full of lens care products.
- (5) DO NOT USE SALIVA, TAP WATER AND BOTTLED WATER.

#### 4. Insertion and removal by the patient

The patient should be instructed on the procedure of insertion and removal of the lens as follows:

Cut the fingernails short and round before handling the lenses. Always wash the hands and fingers with soap, and rinse off completely.

#### [Lens insertion procedures]

Based on the judgement of an Eye Care Practitioner, explain and direct the most suitable procedures. The following examples might be considered.

- (1) Take out a lens from the lens case, pour lens care products, rub it, and wash out by lens care products. Use the same procedure even if it is unused lenses.
- (2) Place the lens on the index finger.
- (3) Put a few drops of artificial tear eye-drops or a similar substance on the concave side of the lens. Be careful not to get air bubble at that time.
- (4) Open the eye wide using the thumb and index finger of the other hand.
- (5) Bring the lens close to the eye slowly, and gently place the lens on the iris of the eye.
- (6) After placing the lens on the iris, slowly release the fingers that were opening the eye, and blink.
- (7) DO NOT USE SALIVA, TAP WATER AND BOTTLED WATER.

#### [Lens removal procedures]

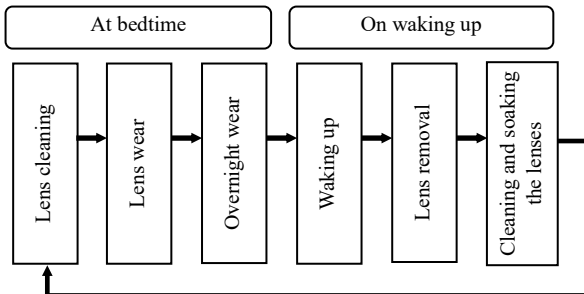
- (1) Apply the artificial tear eye-drops or a similar substance to the eye, and confirm that the lens is on the iris and become movable.
- (2) Press hairlines of the upper and lower eyelashes with both index fingers.
- (3) Lift the finger holding the upper eyelid and hold the top edge of the lens with the upper eyelid. Gently lift the finger holding the lower eyelid and remove the lens with eyelids in a scooping manner.

- (4) Rub the lens by lens care products, wash out by lens care products, and place to the lens case with full of lens care products.
- (5) DO NOT USE SALIVA, TAP WATER AND BOTTLED WATER.

5. Lens wear schedule

[Wearing cycle]

- Wear the lenses longer than 5 hours as standard usage.
- The effects of visual acuity correction vary individually. Instruct each patient to comply with the lens wear schedule properly.



[Wearing schedule (resuming wearing lenses after interruption)]

Instruct the patient to receive eye examination before resuming the lens wear in case of discontinuing for a long time. Referring the cycle above, direct each patient on the lens wear schedule according to their condition.

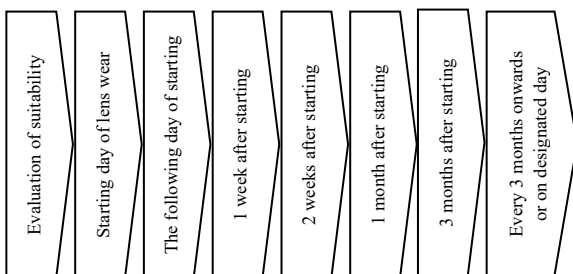
6. Lens care Direction

Instruct the patient on the following regarding lens care. Lens care is essential in order to maintain the performance of the lens and to keep it safe and for comfortable wear. The procedure of the lens care for this product is the same for rigid gas permeable contact lens; however, since its design is unique, be sure to direct your patient about careful cleaning and rinsing, especially the following points.

- (1) Always wash the hands and fingers with soap, and rinse off completely before lens care.
- (2) For lens care, using the compatible lens care products for the rigid gas permeable contact lens, wash the lens by gently rubbing it, and rinse it. Then, put the lens care products into the lens case and immerse the lens completely in the solution (Instruct the patient to remove the protein when many stains are noted on the lens).
- (3) When using the lens care products, read the labels and package inserts with lens care products and follow instructions.
- (4) While the lenses are being used, always empty, wash and rinse the lens case with fresh, and allow to air dry. Replace the lens case at regular intervals.
- (5) DO NOT USE SALIVA, TAP WATER AND BOTTLED WATER.

7. Regular examinations

[Examination schedule]



[Parameters for examinations]

- (1) Interview
- (2) Anterior eye segment examination and funduscopy
- (3) Corneal topography measurement
- (4) Objective refraction test
- (5) Corneal endothelial cell measurement (at least 2,000/mm<sup>2</sup>)
- (6) Tonometry
- (7) Visual acuity test

- (8) Fitting test (confirmation of the lens centering, etc.)
- (9) Examination of appearance of the lenses (See [Aspects concerning maintenance and inspection])

[Item required attention on examination]

- Change the lens specification in case moderate visual acuity is not obtained or lens centering is not good.
- The eye care practitioner should instruct the patients on lens care directions, when the lens is dirty.
- Take the proper action including lens specification change, re-guidance of lens use or stopping or suspending its use as necessary, based on some examination findings.
- Be aware of the possibility that lens wearing may be inappropriate even after the starting of lens wear, patient's physical or visual conditions change due to illness, pregnancy, childbirth, or use of medication, or their life environment changes.

8. Giving instructions to the patient

Be sure to provide the lens wear instruction manual to the patient and instruct him/her to preserve it for reference whenever needed. For safe and comfortable lens wear, the patient should understand the proper handling and management of the lens and care products. Instruct the patient to understand the importance of regular examinations, to discontinue lens wear whenever any abnormality is perceived, and to consult the Eye Care Practitioner immediately. The early detection of disorders can lead to long-term and safe lens wear. The Eye Care Practitioner should provide each patient with appropriate instructions and warnings in accordance with the following points.

[Key points for instruction]

- (1) Be sure to read the instruction manual to the patient, and consult the Eye Care Practitioner if any aspect is not understandable. Use the lens after referring to the instruction manual. Keep the instruction manual at hand so that it can be read whenever need.
- (2) Appropriately use disposable soft contact lenses or glasses for vision correction until visual acuity has been stabilized with these lenses, or until visual acuity returns to previous levels after use of the these lenses is discontinued, or when visual acuity is reduced during day time.
- (3) Check the eyes for hyperemia or unusual eye discharge by looking into a mirror.
- (4) When removing the lenses from the lens case, check them to confirm that there are no abnormalities, including adhesion of foreign substances, defects, damage, stains, or deformations, and then wear the lenses.
- (5) Confirm that you do not have any abnormal sharpness of visual acuity, including dimness, blariness, dazzle, blur, and unstable visual acuity.
- (6) Discontinue lens wear when any abnormality is perceived, including foreign body sensation, hyperemia, pain, and consult the Eye Care Practitioner.
- (7) Discontinue lens wear temporarily when you are physically unwell (e.g., having cold, influenza, etc.).
- (8) Regular check-ups, as determined by the eye care practitioner are also extremely important. Visit the eye care practitioner even if lens wear is comfortable.
- (9) Use artificial tear eye-drops or a similar substance in order to use the lenses safely and comfortably.
- (10) The patient should be reminded to have the required care products when travelling abroad.
- (11) Stains adhering to the lens may vary individually, even if the lens is handled in the same way.
- (12) In contrast with glasses or regular contact lenses, visual acuity may vary depending on wear time, quantity or quality of sleep, etc.
- (13) With respect to driving a car or motorcycle or engaging in tasks where changes in visual acuity are associated with physical and mental risks, do not be involved in these until visual acuity is stabilized.

[Contraindications (REASONS NOT TO USE)]

DO NOT USE the Breath-O Correct when any of the following conditions exist:

- (1) Acute or subacute inflammation or infection of the anterior segment of the eye.

- (2) Eye infections
- (3) Decreased corneal sensitivity
- (4) Severe insufficiency of lacrimal secretion (dry eyes).
- (5) Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of lens care products.
- (6) Signs of keratoconus or other corneal disorders
- (7) Pregnant or breast-feeding women or women planning to conceive
- (8) Immune disorders (e.g., Acquired immune deficiency syndrome and autoimmune disorders) or diabetes mellitus
- (9) Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- (10) Redness of the eyes or irritated.
- (11) Patients who cannot follow the instructions given by an Eye Care Practitioner.
- (12) Patients who cannot undergo regular examinations.
- (13) Patients who always need proper visual acuity at work and who have difficulty in discontinuing their work when changes in vision acuity occur.
- (14) Patients who has unstable corneal refractive power (radius of curvature) measurement or irregular Meyer image (irregular astigmatism)

#### [Warnings]

1. To use Breath-O correct, thoroughly explain the situation, including the issues mentioned below, to the patient and obtains consent and continuously provides the patient with instructions on the proper use of the product.
  - (1) Breath-O correct should be used for overnight wear only.
  - (2) Unaided vision cannot be corrected as intended if these lenses are used improperly. The patient should adhere to the prescribed schedule. When wear is discontinued, unaided vision will be reduced in a few days.
  - (3) Eye disorders including corneal endothelial cell loss or giant papillary conjunctivitis may occur even when Breath-O correct is used properly. The patient should visit the Eye Care Practitioner for regular examinations irrespective of the cognizance of any symptom.
  - (4) Lens wear may increase the risks of eye disorders including corneal ulcer, corneal infiltrates, keratitis, corneal edema, corneal neovascularization, corneal erosion, corneal epithelium disorder, conjunctivitis, allergic conjunctivitis, iritis and stye. Therefore whenever a patient perceives any abnormality, including lacrimation disorder, foreign body sensation, pain, hyperemia, eye discharge, or changes in vision, or finds damage to the lens, immediately discontinue lens wear and promptly consult the Eye Care Practitioner.
2. Improper use of Breath-O correct or the care products may cause serious eye disorders, including corneal ulcer, potentially resulting in sight loss. Cleaning and storage of the lenses should be properly conducted in accordance with the instruction manual.
3. As for tasks where changes in visual acuity are related to physical and mental risks, such as driving a car or motorcycle, the Eye Care Practitioner should decide the patient's involvement and instruct the patient.
4. Warn your patient that if he/she wears any defected lens, or if lens is damaged during he/she wears, be sure to notice to an Eye Care Practitioner even though there is no subjective symptom.

#### [Precautions]

##### [Precautions (Careful administration)]

- (1) At around 40 years of age, presbyopia may develop. Prescribe the lenses to these patients cautiously, because lens wear may cause near vision disturbance and asthenia.
- (2) Carefully prescribe the lenses to the patients who has a large diameter of the pupil in a dark place due to halos or glare symptoms may be occurred. (Appropriate pupil diameter in a dark place is 4 to 5 mm)
- (3) In patients with decisive inverse astigmatism or with oblique astigmatism, use these lenses after thorough examination.
- (4) Be careful at a prescription judgment when the patients uses vision corrective contact lens. (Shape of the cornea might be changed by wearing the vision corrective contact lens)
- (5) If use of eye drop except artificial tear eye-drops is directed, be sure to use it when the patient does NOT wear the lens. (Some components of some eye drop might affect badly to the lens)

- (6) If the patient scratches his/her eyes during sleep, or if the patient sleeps face-down, be careful at a prescription judgment. If there is any problems, the patients should immediately remove the lenses and consult an Eye Care Practitioner. (Lens might be moved inappropriately and the corneal does not be corrected well, so that the targeted corrected vision might not be obtained)

##### [Important notifications]

- (1) To provide safety and appropriate guidance for the patients, the Eye Care Practitioner should attend a course for Orthokeratology as necessary.
- (2) Because the effects of vision correction depending on the duration of wear may vary individually, the wear schedule should be customized for each patient. Instruct the patient to adhere to the schedule.
- (3) When the effects of vision correction are not attained as intended, discontinue lens wear instead of selecting improper lenses that force stronger correction exceeding the target visual acuity.
- (4) Visual acuity will be reduced in a few days if lens wear is discontinued. Instruct the patient to use disposable soft contact lenses or glasses appropriately for vision correction.
- (5) Apply these lenses in patients with myopia or myopic astigmatism having a stable refractive power (changes in myopic diopter during the last year should be  $\pm 0.50$  D or less, or good visual acuity should have been maintained during the same period without any change in the power of glasses or contact lenses). If visual acuity appears to be unstable, more careful treatment should be prescribed. For example, instruct the patient to re-visit later for re-examination.
- (6) Inspect the lens to ensure that the lens does not have any defects such as scratch on the lens surface, damaged, dirt, attached of foreign bodies, discolored, deformed, or damaged.
- (7) Instruct the patients not to use the lens if it has any defects.

##### [Interactions (Precautions for co-administration)]

Prescribe these lenses cautiously to patients on drug therapies that may cause decreased lacrimation (dry eyes) or may affect vision, or those on anti-inflammatory drugs (e.g., corticosteroids), or those who are scheduled to receive these drugs.

##### [Application to the elderly]

- If an elderly patient needs any assistance for the lens insertion or the lens removal, or the lens care, be sure to explain and direct his/her families about the correct procedures well.
- In case an elderly patient has difficulty in lens inserting or removing, or its care by him/herself, determine if the Orthokeratology treatment could be continued or not.

##### [Application to pregnant, parturient, nursing woman or children]

- See [Contraindications] for the use of pregnant, parturient, or nursing woman.
- Safety and validity of these lenses have not been established in minors (Clinical studies were conducted in adults over the age of 20 years).

##### [Other precautions]

- (1) Patients should be informed that the following conditions after lens wear initiation may affect lens wear: any illness, requiring medications or eye drops, or pregnancy.
- (2) Patient with allergic diseases may have allergic reactions on the eye surface or in the ocular appendages more often than other patients. Keratopathy and keratitis are more likely to occur in patients with a history of these diseases than in others.
- (3) Do not sterilize in boiling water. (It can damage or deform the lenses.)
- (4) Be careful if a patient drives a car or a motorcycle, because halos or glare may be occurred even after the patient obtains stable corrected vision.
- (5) Do not use any lens case which does not fit to the product. (The diameter of this lens is bigger than a typical rigid gas permeable contact lens. Thus, the size of the lens holder which is commercially supplied is usually too small. In that case, the commercially supplied lens holder may give too much pressure to this lens, and result in a deformed lens) Use the compatible lens case which does fit to the product.
- (6) Do not re-work or re-create this product.
- (7) Put a few drops of artificial tear eye-drops or a similar substance on the concave side of the lens. Be careful not to get air bubble at that time. (The corneal does not be corrected well, so that the targeted corrected vision might not be obtained)

- (8) Never use well water or tap water to store lenses. (Acanthamoeba in well water or tap water may cause some material disorders of the eye)
- (9) Do not freeze the lens.
- (10) Do not push hard, bend or turn back the lens.
- (11) Explain and direct the patient to hold the lens on the ball of the index finger and the thumb gently.
- (12) Complaints from patients and measures to be taken.
  - [1] The patients may have foreign body sensation, pain, hyperemia, ocular itching, eye discharge or dry eye sensation before they get used to the lens. These symptoms may vary depending on the individual but may disappear in most cases as the patient gets used to the lens. However, the patient should be instructed to visit the Eye Care Practitioner immediately for examination when these symptoms are strong or persist for a long time.
  - [2] Even after getting used to the lens, the symptoms described below may appear. Patients should be instructed to consult the Eye Care Practitioner immediately when these symptoms are not improved by the measures taken or when other symptoms occur.

A) When a lens has a deficiency.

Symptoms	Possible causes	Measures to be taken
Pain Lacrimation	Damage to the lens or Stains on the lens	Discontinue lens wear and visit the Eye Care Practitioner for examination.
Difficulty in seeing Strange sensation in the eye	Deformation of the lens or Reversal of the lens	

B) When an eye has a disease

Symptoms	Possible causes	Measures to be taken
Dry eye sensation	Lack of lacrimation	Discontinue lens wear and visit the Eye Care Practitioner for examination.
Foreign body sensation, pain, or ocular itching during lens wear	Contamination with a foreign body or Eye injury	
Pain or hyperemia after lens removal		Consult the Eye Care Practitioner immediately.

C) When lens usage is inappropriate

Symptoms	Possible causes	Measures to be taken
Strange sensation in the eye	Insufficient cleaning	Wash the lens thoroughly, e.g., wash by gently rubbing it. If symptoms persist even after taking measures, consult the Eye Care Practitioner.
Eye-stinging or excessive lacrimation immediately after lens wear	Stains on the lens	Wash and rinse the lens thoroughly. Check for abnormalities in the lens.
	Residual lens care products (Insufficient rinsing)	Rinse the lens thoroughly.

D) When the prescription is inappropriate

Symptoms	Possible causes	Measures to be taken
Lens are often displaced	Unfitting lens curve	Discontinue lens wear and visit the Eye Care Practitioner for examination.
Blurred vision Diplopia		

**[Potential adverse events]**

The objective findings or symptoms mentioned below may occur with lens wear. Take necessary measures, as needed, including discontinuing lens wear.

- corneal ulcer
- corneal neovascularization
- corneal desquamation
- superficial punctate keratopathy
- corneal staining
- corneal opacity
- corneal warpage (corneal irregular astigmatism)
- corneal foreign body
- papillary conjunctivitis
- allergic conjunctivitis
- conjunctival hyperemia
- iritis
- ciliary hyperemia
- sty
- dry eyes
- eye infection
- halos, glare, loss of visual contrast sensitivity
- dislocation of lens (lens decentration)
- damaged
- deformed
- inside-out
- dirt

**[Storage and Duration of Use]**

[Storage of unopened lenses]

Avoid direct exposure to sunlight and extreme heat. Store the lens at room temperature.

**[Aspects concerning maintenance and inspection]**

At periodic intervals, visual examination of Breath-O contact lenses should be conducted (scratches, stains, and adhesion of foreign materials on the lens surface, and discoloration, deformation, and damage) to determine continuous usability of the product. When continuous use is difficult, take necessary actions such as replacing the product.

**The Breath-O Correct should be expired 6 years and 7 months after manufacturing date.**

**Manufacturer:**

SEED Co., Ltd.

2-40-2, Hongo, Bunkyo-ku, Tokyo 113-8402, Japan

**Authorized Representative / Distributor:**

SEED Contact Lens Malaysia Sdn.Bhd.

No.38, Jalan Puteri 5/8, Bandar Puteri Puchong,

47100 Puchong, Selangor Darul Ehsan, Malaysia





Phone: +603-8051 9889

**Registration Number:**

GB531851277619

**[Symbol Key]**

The following symbols may appear on the label or on the packaging:

Symbol	Definition
	Caution and Attention, see instructions for Use
	Consult to Instructions for Use
	Date of Manufacture
	Lot Number/Batch Code
TRIAL	The device is intended only for the trial lens.
F.T	Fitting Curve
T.P	Target Power
B.C	Base Curve
P	Power for contact lens
S	Lens size (Diameter)