

## 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.

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

##### 1. Before handling lens

- 1) Cut your fingernails short and round before handling your lenses.
- 2) Always wash your hands and fingers with soap, and rinse off completely.
- 3) Do not wet your lens with saliva, bottled water or tap water.
- 4) Work over a table with a clean towel. Do not remove your lenses over a sink.
- 5) Make sure your nails, fingertips and plunger do not touch your eyes directly. They may make a scratch on your eyes.

##### 2. Lens insertion

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

##### 3. Lens removal

###### 1) Scooping method

- 1) Apply the artificial tear eye-drops or a similar substance to the eye, and confirm that your lens is on the iris and becomes 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 your lens with the upper eyelid. Gently lift the finger holding the lower eyelid and remove your lens with eyelids in a scooping manner.
- 4) Rub your lenses by lens care products, wash out with lens care products, and place to the lens case with full of lens care products.

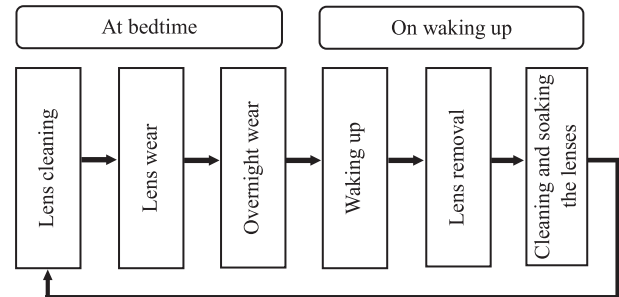
###### 2) Suction cup method

- 1) Apply the artificial tear eye-drops or a similar substance to the eye, and confirm that your lens is on the iris and becomes movable.
- 2) Hold the suction cup by thumb and index finger of your dominant hand.
- 3) Open both eyes wide while looking in the mirror, and make sure that your lenses are placed on your eyes.
- 4) Lightly push the suction cup straight in the center of your lens.
- 5) Lower the suction cup and remove your lens from the eyes, with attention not to close the eyes.

##### 4. Lens wear schedule

###### 1) Wearing cycle

- (1) Wear your lenses longer than 5 hours as standard usage.
- (2) The effects of visual acuity correction vary individually. Follow the instructions of your Eye Care Practitioner and be sure to comply with the lens wear schedule properly.



###### 2) Resuming wearing lens after interruption

Receive eye examination before resuming lens wear in case of discontinuing for a long time. Referring to the cycle above, follow the instructions of your Eye Care Practitioner on the lens wear schedule.

##### 5. Maintenance

###### 1) Lens care

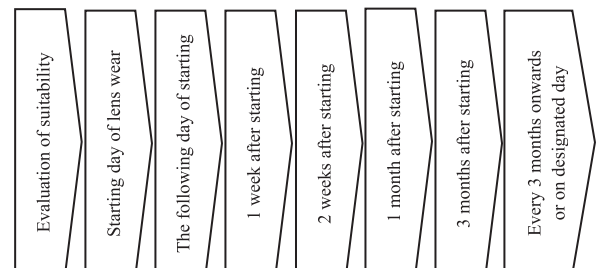
- (1) Always wash your hands and fingers with soap, and rinse off completely before lens care.
- (2) For lens care, using the compatible lens care products for the orthokeratology contact lens, wash your lenses by gently rubbing them and rinse them. Then, put the lens care products into the lens case and immerse your lenses completely in the solution.
- (3) When using the lens care products, read the labels and package inserts of lens care products and follow instructions.
- (4) Replace your lenses with new ones every two years as standard usage, but please follow the instructions of your Eye Care Practitioner about frequency.

###### 2) Managing the lens case

- (1) Be sure to use a dedicated lens case for the orthokeratology contact lens.
- (2) Replace your lens case with a new one every three months as standard usage.
- (3) Dispose the disinfectant solution from the lens case. Wash and air dry the lens case completely.

##### 6. Regular examination

- 1) If you experience even a slight abnormality, immediately contact your Eye Care Practitioner for an eye examination.
- 2) Make sure to regularly receive eye examinations as instructed by your Eye Care Practitioner and have him/her check if your lenses can be used, even if you are wearing contact lenses comfortably without any symptoms.



### [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. Read these instructions thoroughly prior to the use of contact lenses and lens care products. If there are any unclear explanations or contents, consult your Eye Care Practitioner before use.
  - 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, consult your Eye Care Practitioner and follow the instructions.
4. If you have worn a damaged lens or a lens has been damaged during use, immediately contact your Eye Care Practitioner for an eye examination even if you do not notice any symptoms.

### [Precautions]

1. Precautions to ensure safety of your eyes
  - 1) Before inserting your lenses in your eyes, examine your lenses to make sure that they are not damaged, deformed, or scratched, and are free of any foreign substances or dirt. Never use lenses with any such defects.
  - 2) Follow the instructions of your Eye Care Practitioner in regard to the use of eye-drops.
  - 3) Do not rub or press your eyes with force while wearing contact lenses.
  - 4) Use only lenses prescribed for yourself.
  - 5) Never use well water or tap water to store your lenses. The acanthamoeba in well water or tap water may lead to serious eye disorders. Use the lens care products to store your lenses.

2. Precautions to protect your lenses from damage, deformation, scratches, foreign bodies, and dirt

- 1) Cut your fingernails short with their tips round and smooth.
- 2) Wash your hands and fingers with soap and rinse off the soap completely before handling your lenses.
- 3) Place a washed towel or handkerchief on a well-lit, clean surface where you are going to handle your lenses.
- 4) It is best to insert your lenses before applying makeup.
- 5) Do not press, bend, or turn over your lenses with force.
- 6) Use the tips of your thumb and index finger to hold your lens gently.
- 7) If your lens falls out of your eye, wet the tips of your fingers and pick up your lens.
- 8) Do not rub or wipe your lenses with a handkerchief, spectacle wipe, or tissue paper.
- 9) Do not get chemicals or oil, such as cosmetics, hair spray, benzine, alcohol, or thinner, on your lenses.
- 10) Do not soak your lenses in hot water or leave them where they may be subjected to high temperature.
- 11) Do not dehydrate your lenses.
- 12) Do not freeze your lenses.
- 13) Do not hit your lenses against the edge of the lens case, etc.
- 14) Do not use a lens case which can cause deformation of your lenses.
- 15) Do not use your lenses to expand the lens holder when storing your lenses in the holder of the lens case. Doing so may cause damage or deformation of your lenses.
- 16) Do not open/close the cap of a lens care product or lens case while holding your lens with fingers.
- 17) Always keep the lens case clean.
- 18) Do not use saliva to wet your lenses.

3. Other precautions

- 1) If you are hospitalized or recover from an illness or injury, you may not be able to use lenses. Inform your doctor that you are wearing lenses and follow their instructions.
- 2) Never process or alter your lenses.
- 3) Always insert the correct lens in each eye.
- 4) Pay special attention when applying eye-drops over the lenses. The lenses may fall out easily.
- 5) If your eyes feel dry, blink your eyes intentionally.
- 6) Avoid operating a motor vehicle or machinery until you get used to wearing your lenses.
- 7) Purchase replacement lenses regularly as instructed by your Eye Care Practitioner. (It is said that lenses should be replaced with new ones every two years as standard usage.)
- 8) Purchase replacement lens cases regularly.
- 9) Keep your lenses out of reach of children.
- 10) If an elderly user finds it difficult to insert/remove, or care for lenses, consult an Eye Care Practitioner and follow the instructions.
- 11) Physical conditions or status of the eyes due to illnesses, medications, or eye-drops may affect contact lens wear, even if they do not fall under the symptoms listed in [Contraindications]. Consult your Eye Care Practitioner before use. Also, the condition of contact lens wear may change after starting to use lenses. Consult your Eye Care Practitioner for details.
- 12) Check the eyes for hyperemia or unusual eye discharge by looking into a mirror. Discontinue lens wear when any abnormality is perceived, including foreign body sensation, hyperemia, pain, and consult your Eye Care Practitioner.
- 13) Symptoms and measures to be taken.
  - (1) You may experience any of the following physiological symptoms during the initial stage of contact lens wear. The symptoms may resolve as your eyes become used to your lenses (generally after a few weeks). -- Minor foreign body sensation in your eyes
    - Excessive eye blinking
    - Ocular itching
    - Excessive lacrimation
    - Unusual eye discharge
    - Sensitivity to light
    - Unstable vision
    - Dizzy

(2) Even after getting used to your lenses, the symptoms described below may appear. You should 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 a 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
- styte
- 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 9 months after manufacturing date.**

**[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)