

INSTRUCTION FOR USE

Device / Model Name:	Power	B.C	DIA	Thickness
Sterile soft contact lens for daily wear, reusable.	+20.00 D ~ -20.00 D	8.3~9.0 mm	14.0 ~ 15.0 mm	0.07 ~ 0.34 mm

Please refer to the packaging label for specific product specification

Contents: Daily wear soft contact lenses immersed in isotonic saline solution

Indication: Myopia, hyperopia

Intended use

Corrective lenses are intended for daily wear to correct vision of myopia and hyperopia in people with non-diseased eyes.

Intended patient population: Any patients who need eye-sight correction. Age is 10~70 years old. Gender, Weight Race is not relevant.

Replacement Schedule: Refer to the packaging label

Intended user: Lay person (Ordinary people who need vision correction)

Intended use environment: The device is a soft contact lens intended to be worn on the human cornea for vision correction. Initial fitting and instruction are provided by an eye-care professional in a clinical setting; routine insertion, removal, cleaning, storage and disposal are performed by the user in non-clinical environments (home, workplace, school) under normal ambient conditions (room temperature, typical indoor/outdoor lighting and humidity). Users must follow product-specific Instructions for Use (IFU) provided by the manufacturer

Notices

1) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

Precautions

- Follow the eye care professional's instructions for duration of use of the contact lens on a daily basis, follow-up visits, and emergency procedures.
- Contact lenses should be removed immediately after contact with noxious vapour (e.g. chemical or hazardous substances) or hazardous environment with ocular impact.
- Direct exposure of contact lenses to non-sterile water (e.g. tap water, whirlpool bath, swimming, participating in water sports) increases the risk of microbial infection.
- The use of non-sterile water (e.g. tap water) in the handling of contact lenses and contact lens cases increases the risk of serious microbial infection
- Do not change lens type or parameters without consulting an eye care professional.
- Do not use if the blister is damaged or seal is broken
- In the event of a **side effect** to the wearing of the contact lens, the user should immediately remove the contact lens and consult an eye care professional before resuming use
- Aphakic patients should not be fitted with contact lenses until the determination is made that the eye has healed completely.
- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
- Never use solutions recommended for conventional hard contact lenses only.
- Chemical disinfection solutions should not be used with heat unless specifically indicated on product labeling for use in both heat and chemical disinfection.
- If the lens sticks (stops moving or cannot be removed), the patient should be instructed to apply 2 to 3 drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it. If non-movement of the lens continues more than 5 minutes, the patient should immediately consult 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-base 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, cleaning disinfecting, storing and wearing instructions in the Patient instructions for the Contact lens and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has steered.
- Always handle lenses carefully and avoid dropping them.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- 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.
- When wearing lenses that alter the eye color, temporary differences in the vision due to the presence of the color in the lens may be noticed especially in conditions of low light. If these differences in vision persist when wearing contact lenses, it is important to contact the eye care practitioner.
- Do not change the contact lens care system without consulting an eye care professional.
- Do not share contact lenses with others.
- Remove your lenses before you go to bed.
- When vision prescriptions between two eyes are different, be careful not to switch the right and left contact lenses.
- Replace your lenses if they become uncomfortable, cause blurry vision, or show signs of damage like scratches or tears.
- Do not flush them down the toilet or sink, and instead, dispose of them in the regular trash.
- Children and elderly people can successfully wear contact lenses under the supervision of an ECP or with parental supervision.

Side effect

The patient should be informed that the following problems may occur:

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

Warning

- The tinted contact lens can reduce visibility in low light conditions
- The wearing of the contact lens while sleeping increases the risk of infection and permanent damage to vision

Contraindications

Do not use contact lenses when any of the following conditions exist:

- Acute and sub-acute inflammation or infection of the anterior chamber of eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids.
- 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.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for the contact lens.
- Any active corneal infection (bacterial, fungal, or viral).
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so.

Inserting the lens into your eye

- Rinse your lenses with multi-purpose solution before you put them on
- Put one of the lenses on the tip of your index finger. Make sure the lens is in a bowl shape; if not flip the lens inside out.
- Hold the upper eyelid from above with one finger of your left hand.
- Place the lens carefully on the middle of the cornea, holding the lower eyelid down with the middle of the right hand.
- Slowly release upper eyelid, look down and gently close your eye.
- Repeat the same procedure for the other eye.

Removing lens from your eyes

- You may want to use a lubricating and rewetting drop just before you remove your lenses.
- One or two drops in each eye will moisten the lenses and make them easier to remove.
- Look up, holding your lower eyelid down. Pull the lens downward gently with your index finger and your thumb. Pinch the edge of the lens and remove it from your eye.
- Repeat the same procedure for the other eye.

Disinfections

- Before inserting the lens after removing it from the eye, always rinse the lens with contact lens solution suggested by your practitioner.
- After wearing your lenses, store them in a case filled with fresh contact lens solution and keep the storage case clean.
- If you do not wear your lenses frequently, change the contact lens solution in the case with fresh solution once a week.
- For removal of protein, do removal more than once a week by using protein remover or exclusive soaking solution which has a full removal function of protein.

Washing

- Put the lens in the palm of the hand.
- Drop the exclusive washing solution to 1-2 drops.
- Rub lightly by turns to both sides of the lens.
- Rinse cleanly with the saline.

List of other products which are intended to be used in combination with the device

Lens solution (contact lens care product)

- Polyhexamethylene biguanide-based solution

- Product name: Renew Fresh
- Manufacturer: Bausch & Lomb Incorporated

- Hydrogen peroxide-based solution

- Product name: Aosep + (hydrogen peroxide)
- Manufacturer: Alcon Research, Ltd.

Manufacturer & EC representative

DreamCon Co., Ltd.

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Information of Symbol



Manufacturer



Authorized representative in the European



Date of manufacture



Use-by date



Batch code



Sterilized using steam



Consult instructions for use



Single sterile barrier system



Medical Device



Unique device identifier



Do not use if package is damaged and consult instructions for use



Keep away from sunlight



Keep dry or Keep away from rain



Base curve



Spherical Power / Label back vertex power



Total Diameter



Importer