Ray-Ban Disposable Soft Contact Lenses

Instruction for Use

IMPORTANT: Please read carefully and keep this information for future use. This intruction for use is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

This IFU is applicable to the following products:

No.	Product Name	Material	Modality	UV Blocker
1	Ray-Ban 1-Day Premium	stenfilcon A	Daily	Yes
2	Ray-Ban 1-Day Premium Toric	stenfilcon A	Daily	Yes

SYMBOLS KEY

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION
	Caution: this device to sale by or on the order of a licensed practitioner
	Caution / See Instructions for Wearers
	Use by Date (expiration date)
	Batch Code
	Sterile using Steam Heat
	UV Blocking
	Manufacturer
	Do not use if package is damaged
	Consult instructions for use / consult electronic instructions for use
	Do not re-use
	Date of manufacture

DESCRIPTION

Contact Lenses are available as an Asphere/Sphere, Toric, Multfocal and Multifocal Toric lens designs. The materials of the contact lens can be found on product package.

For contact lens with UV blocking symbols key on packaging only:

Contact lenses contain a UV blocker help protect against transmission of harmful UV radiation to the cornea and eye.

WARNING: 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 the surrounding area. You should continue to use absorbing eyewear as directed.

Long term exposure to the 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 the outdoor activities). UV-absorbing contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

ACTIONS

When placed on the cornea in its hydrated state, the Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS FOR USE

ASHPERE and SPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00D to +20.00D diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MULTIFOCAL TORIC Soft Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic which, possess astigmatism to -5.75 diopters or less, and are presbyopic.

CONTRAINDICATIONS (REASONS NOT TO USE):

Do not use the 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.
- 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.

WARNINGS

Patients should be advised of the following warnings pertaining to contact lens wear:
PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that patients follow their eye care practitioner's directions 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 these 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 discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eyecare practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners

- Due to the small numbers of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Patients who wear aspheric contact lenses to correct presbyopia may not achieve the best corrected visual acuity for either far or near vision. Visual requirements vary with the individual and should be considered when selecting the most appropriate type of lens for each patient.
- Aphakic patients should not be fitted with any CooperVision contact lenses until the determination is made that the eye has healed completely.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb the dye and become discolored. Whenever fluorescein is used in the eyes, the eyes should be flushed with a sterile saline solution that is recommended for in-eye use.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove the lenses or should have someone else available who can remove the lenses for him or her. Eye care practitioners should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.

Eye care practitioners should carefully instruct patients about the following safety precautions:

- Always discard disposable lenses after the recommended wearing schedule prescribed by the Eye Care Practitioner.
- The compatibility of the lens with lens care regimens has not been evaluated.
- Do not use saliva or any solutions for lubricating or wetting lenses.
- 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 non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorant, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to damage lenses than oil-based products.
- Do not touch the contact lenses with the finger or hands if the hands are not free of foreign materials, as lens damage may occur.
- Carefully follow the handling, insertion, removal, and wearing instructions in the Patient Instructions for contact lenses 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 hairspray 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.
- Avoid rubbing eyes with the lenses on, this can irritate eye or dislodge the lens.
- Ask the eye care practitioner about wearing the lenses during sporting activities.
- Always follow the directions in the package inserts for the use of contact lens solutions.
- Lenses prescribed on a daily disposable wearing schedule should always be discarded when removed at the end of the wearing day.
- 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 hand.
- Do not touch the lens with fingernails.
- 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.

ADVERSE REACTIONS

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, 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 the lenses.**
- If the discomfort or the 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. Place the lens in a storage case and contact the eye care practitioner. Daily disposible lenses should not be reinserted. If the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner**.
- When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. The patient should be instructed to **keep the lens off the eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Practitioner(according to modality definition recommended by product owner). Patients tend to over-wear 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.
CooperVision recommends that all daily disposable lenses be discarded and replaced with a new lens on a daily basis.

INSTRUCTIONS FOR LENS HANDLING

Preparing the Lens for Wearing

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:
Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses. These substances may contact the lenses and interfere with successful wearing.
Handle your lenses with your fingertips. Be careful to avoid touching the lens with fingernails. It is helpful to keep your fingernails short and smooth.
Start correctly, always use proper hygienic procedures.

Lens Package

The individual package is designed specifically to maintain sterility. The lens packages are individual.
To open an individual lens package, follow these simple steps:
Shake the lens package and check to see that the lens is floating in the solution.
Peel back the foil closure to reveal the lens. Stabilizing the lens package on the tabletop will minimize the possibility of a sudden splash.
Occasionally upon opening, a lens may adhere to the inside surface of the foil or to the plastic package itself. This will not affect the sterility of the lens and it is still perfectly safe to use. Carefully remove and inspect the lens by following the handling instructions.

Handling the Lenses
Develop the habit of always working with the right lens first to avoid mix-ups.
Remove the right lens from its storage case and examine it to be sure that it is moist, clean, clear and free of any nicks or tears. If the lens appears damaged, do not use it. Use a new lens.
Verify that the lens is not turned inside out by placing it on your forefinger and checking its profile. The lens should assume a natural, curved, bowl-like shape (Fig. A). If the lens edges tend to point outward, the lens is inside out (Fig. B).
Another method is to gently squeeze the lens between the thumb and forefinger. The edges should turn inward (Fig A). If the lens is inside out, the edges will turn slightly outward (Fig. B).

Fig. A

Fig. B

Placing the Lens on the Eye
Start with your right eye.
Once you have opened the lens package and removed and examined the lens, follow these steps to apply the lens to your eye:
Place the lens on the tip of your forefinger. BE SURE THE LENS IS CORRECTLY ORIENTED (see "Handling the Lenses").
Place the middle finger of the same hand close to your lower eyelashes and pull down the lower lid (Fig. C).
Use the forefinger or middle finger of the other hand to lift the upper lid.
Place the lens on the eye (Fig. D).
Gently release the lids and blink. The lens will center automatically.
Use the same technique when inserting the lens for your left eye.
If the above method is difficult for you, your Eye Care Practitioner will provide you with an alternate lens replacement method.

Fig. C

Cornea

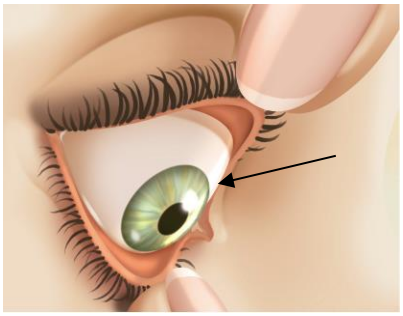
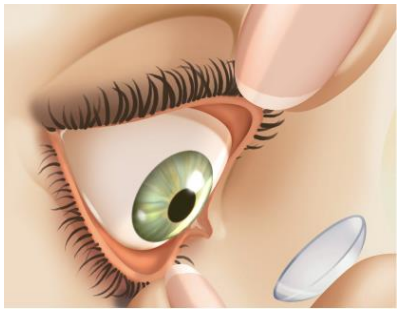


Fig. D



Note:If after placement of the lens your vision is blurred, check for the following:
The lens is not centered on the eye ("Centering the Lens").
If the lens is centered remove the lens ("Removing the Lens") and check for the following:
a. Cosmetics or oils on the lens. Clean the lens.
b. The lens is on the wrong eye.
c. The lens is inside out (it would also not be as comfortable as normal).
If you find your vision remains blurred after checking the above possibilities, remove both lenses and consult your Eye Care Practitioner.

After you have successfully inserted your lenses, you should ask yourself:
How do the lenses feel in my eye?
How do my eyes look?
Do I see well?
If your examination shows any problems IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYE CARE PRACTITIONER.

Centering the Lens
A lens on the cornea (center of your eye) will rarely be displaced onto the white part of the eye during wear. This can occur if insertion or removal procedures are not properly performed. To center a lens follow either of these procedures:
Close your eyelids and gently massage the lens into place through the closed lids.
OR
Gently manipulate the off-centered lens onto the cornea while the eye is open, using finger pressure on the edge of the upper lid or lower lid.

Removing the Lens
CAUTION: Always be sure the lens is on the cornea before attempting to remove it. Determine this by covering the other eye. If vision is blurred, the lens is either on the white part of the eye or it is not on the eye at all. To locate the lens, inspect the upper area of the eye by looking down into a mirror while pulling the upper lid up. After, inspect the lower area by pulling the lower lid down.
Wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
Remove the right lens first. There are two recommended methods of lens removal: the Pinch Method and the Forefinger and Thumb Method. You should follow the method that your Eye Care Practitioner recommends.

Pinch Method for removing lens:
Look up and slide the lens to the lower part of the eye using the forefinger. (Fig. E)
Gently pinch the lens between the thumb and forefinger. (Fig. F)
Remove the lens.

Fig. E	Fig. F
	

Forefinger and Thumb Method for removing lens:
Place your hand or a towel under your eye to catch the lens.
Place your forefinger on the center of the upper lid and your thumb on the center of the lower lid.
Press in and force a blink. The lens should fall onto your hand.
Once you remove the lens, simply follow the lens care directions recommended by the Eye Care Practitioner.
Note: The lens may come out but remain on the eyelid, finger or thumb.
Remove the other lens by following the same procedure.
Follow the required lens care directions.
Note: If these methods of removing your lenses are difficult for you, your Eye Care Practitioner will show you with an alternate method.

WEARING SCHEDULES

Record here the number of hours your eye care practitioner recommends you wear the lenses each day during the adaption period. Typically, soft contact lens patients should be able to wear their lenses 6 hours the first day, 8 hours for the second day, 10 hours for the third day, 12 hours for the fourth day, 14 hours on the fifth day and to all waking hours on the sixth day. Build-up of wearing time is important and you must follow your eye care practitioner's directions.

Prescribed Wearing Schedule for Adaptation to contact lenses

Day	Wearing Time (Hours) **Recommended by Eyecare Practitioner**
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

LENS CARE DIRECTIONS

Daily Wear:

The Soft (Hydrophilic) Contact Lenses are indicated for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.
Eye care practitioners should review with the patient lens care directions, including basic lens care information in accordance with patients lens type and wearing schedule.

- Always wash, rinse, and dry hands before handling contact lenses.
- Do not use saliva or any solutions for lubricating or rewetting. Do not put lenses in the mouth.
- The patient should always have a spare pair of lenses at all times.

- Eye care practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

LENS CARE DIRECTIONS

Frequent Replacement Lenses:

(For Bi-weekly and Monthly contact lens Only)

General Lens Care:

Basic Instructions:

- Always use fresh, unexpired lens care solutions.
- Use the recommended chemical (not heat) system of lens care and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe to use with all lenses. Do not alternate or mix lens care systems unless indicated on solution labeling.
- Lenses should be cleaned, rinsed, and disinfected each time they are removed. Cleaning and rinsing are necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs.
- Always remove, clean, rinse, (as recommended by the eye care practitioner) and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme cleaner is not recommended.
- The eye care practitioner should recommend a care system that is appropriate for the product. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed.
- Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow directions.
- Clean one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfection solution to remove cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, and rinsing, disinfect lenses using the system recommended by the manufacturer and/or Eye Care Practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately following disinfection, the patient should be instructed to consult the package insert or the eye care practitioner for information on the storage of lenses.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the lens case is used again, refill it with storage solution. Replace the lens case at regular intervals as recommended by the lens case manufacturer or your Eye Care Practitioner.
- Eye Care Practitioners may recommend a lubrication/rewetting solution, which can be used to wet (lubricate) the lenses while they are being worn to make them more comfortable.

CHEMICAL LENS DISINFECTION (Including Hydrogen Peroxide):

(For Bi-weekly and Monthly Only)

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the eye care regimen recommended by the lens manufacturer or the Eye Care Practitioner.
- When using hydrogen peroxide lens care systems, lenses must be neutralized before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- When using hydrogen peroxide lens care systems, the patient must use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution. Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling exclusively. Following disinfection with a peroxide system, the lenses should be rinsed with sterile saline. Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- Do not heat the disinfection solution and lenses.
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- CAUTION: Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement in the eye should reduce the potential for irritation.

LENS CASE CLEANING AND MAINTENANCE

(For Bi-weekly and Monthly Only)

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, and rinsed with solution recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or the Eye Care Practitioner.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any lens is exposed to air while off the eye, it may become dry and brittle. In this event, simply dispose of the lens and replace with a fresh one.

CARE FOR A STICKING (NONMOVING) LENS

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.

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 THE EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is supplied sterile in a blister containing buffered saline solution. The blister is labeled with the base curve, diameter, dioptic power, manufacturing lot number, and expiration date of the lens. When applicable, the blister is also labeled with add power, cylinder power and cylinder axis for toric lenses, multifocal add for multifocal lenses, and the presence of a UV-blocker is noted.

DO NOT USE IF THE blister IS BROKEN OR THE SEAL HAS BEEN DAMAGED

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions obseved in patients wearing any contact lens or experienced with the lenses should be reported to:

【Local Responsible Person】
CooperVision (HK) Ltd.
Unit Nos. 1805-1806, Level 18, 909 Cheung Sha Wan Road, Kowloon, Hong Kong
Telephone: (852) 37180699
Fax: (852) 24261177

【Manufacturer】
CooperVision,Inc.
711 North Road, Scottsville, New York 14546, USA

【Manufacturing Site】

1) **CooperVision, Inc.**
   711 North Road, Scottsville, New York 14546, USA
2) **CooperVision Manufacturing Ltd.**
   South Point, Hamble, Southampton, S031 4RF, United Kingdom
3) **CooperVision CL KFT**
   Gorcsev Iván street 7, Building C, 2360 Gyál, Hungary
4) **CooperVision Manufacturing Puerto Rico LLC**
   500 Road 584, Lot 7, Amuelas Industrial Park, Juana Diaz, 00795 Puerto Rico, USA
5) **CooperVision Manufacturing Costa Rica, SRL**
   Zona Franca El Coyol, Building 53, Alajuela 20101, Costa Rica