



CooperVision™

PROCLEAR 1-DAY[®]
(*omafilcon A*)

DAILY DISPOSABLE

HYDROPHILIC CONTACT LENSES

FOR DAILY WEAR

PATIENT INSTRUCTIONS

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PATIENT/EYECARE PRACTITIONER INFORMATION

You have just received your new PROCLEAR 1-DAY (*omafilcon A*) Soft (hydrophilic) Contact Lenses for daily wear. Please read this guide carefully and follow the instructions so that you receive full satisfaction from your lenses

This patient instruction guide is the personal property of:

Name _____ Date _____

PRACTITIONER Name _____

Street _____ City _____

State _____ Zip Code _____ Telephone _____

RECOMMENDED LENS CARE SOLUTIONS

Cleaning _____

Rinsing _____

Disinfection/Storage _____

Lubricating _____

Other _____

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYECARE PRACTITIONER

GLOSSARY

CORNEA	The transparent part of the eye covering the iris (colored part) and pupil (black central area)
DAILY WEAR	The wearing of a contact lens during waking hours only (removed during sleep)
EXTENDED WEAR	The wearing of a contact lens for more than 24 hours (during sleep) without removal PROCLEAR 1-DAY lenses are not to be worn for extended wear
DEHYDRATION	A lens that has dried out and become brittle
HYDROPHILIC	"Water-Loving" – A hydrophilic contact lens absorbs water as part of its material structure
PHOTOPHOBIA	Sensitivity to light
VISUAL ACUITY	Sharpness of vision
EVAPORATIVE TEAR DEFICIENCY	Loss of tear volume due to evaporation
AQUEOUS TEAR DEFICIENCY (NON-SJOGREN'S)	<p>A decrease in the amount of tears There are many causes for this decrease, some are:</p> <ul style="list-style-type: none">• Hormonal changes associated with aging• Environmental factors• Allergies• Lack of Vitamin A• Various medications

PATIENT INSTRUCTIONS

For PROCLEAR 1-DAY (*omafilcon A*) Soft (hydrophilic) Contact Lenses

INTRODUCTION

This Wearer's Instruction booklet has been developed for wearers of PROCLEAR 1-DAY (*omafilcon A*) Soft (hydrophilic) Contact Lenses for Daily Wear.

PROCLEAR 1-DAY lenses are soft (hydrophilic) contact lenses which differ from conventional hard contact lenses in that they become soft and flexible when saturated with water or tears. When fully hydrated, the lens is 60% water.

Your eyecare practitioner will review the proper care and handling of your contact lenses. To obtain maximum performance and satisfaction from your new PROCLEAR 1-DAY lenses, you should carefully follow instructions, adhere to the wearing schedule, and keep all appointments for periodic follow-up examinations recommended by your eyecare practitioner. If you are in doubt about any of the instructions, ask your eyecare practitioner for clarification.

PRODUCT DESCRIPTION

PROCLEAR 1-DAY (*omafilcon A*) Soft Hydrophilic Contact Lenses are a hemispherical shell available in the following dimensions:

LENS PARAMETERS AVAILABLE

Chord Diameter	13.0 mm to 15.5 mm
Base Curve	8.00 mm to 9.50 mm
Powers	-20.00 D to +20.00 D
Cylinder Powers	-0.50 D to -10.00 D as applicable
Axis	1° to 180° as applicable
Add Power Range	+0.25 D to +5.00 D as applicable
Center thickness	0.035 mm to 0.96 mm (varies with power and lens design)

ACTIONS

In its hydrated state, the soft contact lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

WEARING RESTRICTIONS AND INDICATIONS (USES)

PROCLEAR 1-DAY *Sphere* and *Asphere*: PROCLEAR 1-DAY Sphere and Asphere (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.

PROCLEAR 1-DAY *Toric*: PROCLEAR 1-DAY Toric (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who have astigmatism of 2.00D or less and does not interfere with visual acuity.

PROCLEAR 1-DAY *Multifocal*: PROCLEAR 1-DAY Multifocal (*omafilcon A*) Soft (hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in not aphakic persons with non-diseased eyes. The lens may be worn by persons who have astigmatism of 2.00D or less that does not interfere with visual acuity.

PROCLEAR 1-DAY (*omafilcon A*) Soft (hydrophilic) Contact lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

The PROCLEAR 1-DAY (*omafilcon A*) Contact Lenses described in this booklet should be discarded after daily use as prescribed by your eyecare practitioner **DO NOT WEAR YOUR PROCLEAR 1-DAY DAILY WEAR CONTACT LENSES WHILE SLEEPING.**

CONTRAINDICATIONS (REASONS NOT TO USE)

Do not use this contact lens when any of the following conditions exists:

- Previously diagnosed primary Sjogren's Syndrome Tear Deficiency, Autoimmune connective tissue disease which may involve secondary Sjogren's syndrome. Such conditions include rheumatoid arthritis, polyarthritis, Wegener's granulomatosis, systemic lupus erythematosus, systemic sclerosis, primary biliary cirrhosis, and mixed connective tissue disease.
- Acute and subacute inflammation between the lens, iris, and cornea, i.e., the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or

eyelids

- Any active corneal infection purulent (pus) bacterial, fungal, or viral infection
- Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses
- Allergy to any ingredient, such as thimerosal or mercury, in a solution which must be used to care for the lens
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- If eyes become red or irritated

WARNINGS

Patients were not studied who exceed the conditions characterized by any of the following diagnostic parameters:

- Rose Bengal staining > 12 on a scale of 18
- Fluorescein staining >12 on a scale of 15
- Meibomian gland dysfunction >3 on a scale of 0-4

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eyecare 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 you should not 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 you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove your lenses and promptly contact your eyecare practitioner.

PRECAUTIONS

- Before leaving the eyecare practitioner's office, you should be able to promptly remove lenses easily or should have someone else available to remove the lenses for you.

- You should remove the lenses immediately if the eye becomes red or irritated.
- Always wash and rinse your 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, storing and wearing instructions in the Patient Instructions for the PROCLEAR 1-DAY Contact Lens and those prescribed by the eyecare practitioner.
- Never wear lenses beyond the period recommended by the eyecare practitioner.
- Do not use saliva or anything other than the recommended solutions to wet your lenses.
- If aerosol products such as hair spray while are used wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- To prevent your lenses from becoming dry (dehydrated), always keep them completely immersed in the recommended storage solution when the lenses are not being worn. Discard the lens if your lens surface does become dry (dehydrated).
- If the lens sticks (stops moving) on the eye, follow the directions on Care for a Sticking Lens. The lens must move freely on the eye for continued health of the eye. If non-movement of the lens continues, you should immediately consult your eyecare practitioner
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Never use tweezers or other tools to remove the lens from the lens container. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always handle lenses carefully and avoid dropping them.
- Ask the eyecare practitioner about wearing lenses during sporting activities.
- Always inform the doctor (health care practitioner) that you wear contact lenses.
- Always consult your eyecare practitioner before using any medicine in your eyes.
- Always inform employer of being a contact lenses wearer. Some Jobs may require use of eye protection equipment or may require that patient not wear contact lenses.

- As with any contact lens, follow-up visits are necessary to assure health. You should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS (POTENTIAL PROBLEMS)

The following adverse effects have been recognized as potential problems with the use of soft contact lenses:

- Eyes sting, burn, or itch (irritation) or other eye pain
- Comfort is less than when lens was first placed on eye
- Feeling of something in the eye (foreign body, 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 you notice any of the above, you should IMMEDIATELY REMOVE YOUR LENSES.

- If the discomfort or problem stops, look closely at the lens. If the lens is in any way damaged, DO NOT put the lens back on your eye. Place the lens in the lens case and contact your eyecare practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses, then reinsert them. If the problem continues, DO NOT put the lens back on your eye, immediately consult your eyecare practitioner.

WHEN ANY OF THE ABOVE SYMPTOMS OCCUR, A SERIOUS CONDITION SUCH AS INFECTION, ABRASION, CORNEAL ULCER, NEOVASCULARIZATION, UVEITIS, OR IRITIS MAY BE PRESENT. You should keep lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

CLINICAL TEST RESULT

Dry Eye patients have been categorized in the Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes, published in the CLAO Journal, October 1995, Vol 21, No. 4.

The Safety and Effectiveness of the PROCLEAR 1-DAY (*omafilcon A*) soft contact lens is defined. Dry eye patients were demonstrated by the results of a clinical trial which are summarized here. The study patients' dry eye condition is defined as arising from

Evaporative Tear Deficiency or from Aqueous Tear Deficiency* (non-Sjogren's only). Lenses were not tested in subjects having severe cases of Dry Eye syndrome. All subjects were existing contact lens wearers, who met the Dry Eye diagnostic inclusion criteria. See your eyecare practitioner for details of the inclusion criteria.

Overall, the subjects wearing PROCLEAR 1-DAY (*omafilcon A*) lenses reported improved lens performance to that reported for the Control lenses, with the differences in performance becoming more marked as the period of post-fit time increased. This performance data was collected using patient ratings of descriptions of eye symptoms. For each symptom the subject was asked to indicate the frequency or severity of the symptom. Test data shows patients wearing PROCLEAR 1-DAY (*omafilcon A*) lenses reported wearing lenses longer, more comfortably with more feelings of moistness of the eye, and less frequent dry eye symptoms. The results for comfort are further supported by the reduced frequency of occurrence of various symptoms which detail Comfort eye irritation, eye itchiness, burning, grittiness, watering and light-sensitivity. Variation in eye sensations throughout the day and noticeability of eye symptoms were categorized as occurring less frequently while wearing the PROCLEAR 1-DAY (*omafilcon A*) contact lenses.

* See glossary for definitions

PERSONAL CLEANLINESS FOR LENS HANDLING

1 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, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2 Handling the Lenses

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.

3 Placing the Lens on the Eye

The insertion method described below is recommended because it reduces the chances of eye injury and/or lens damage. However, if you find this method difficult, your eyecare practitioner will give you additional instruction or suggest another method:

- After thoroughly washing, rinsing, and drying your hands, and inspecting the lens, place the right lens on the tip of your right index finger (left index finger if you are left-handed). Make sure your index finger is dry (if the finger is wet, surface tension will make the lens adhere to your finger preventing the lens from being transferred from the finger to the eye).

- Pull the lower lid of your right eye downward with the middle finger of your right hand.
- Pull the upper lid of your right eye upward with the middle finger of your left hand. Look straight ahead and gently place the lens directly on the cornea.
- Look down and slowly remove your right hand, releasing your lower lid.
- If there is an intimal foreign body sensation, look toward your nose and slide your lens off the cornea away from the nose. Then look away from your nose toward the lens until the lens reposition itself on the cornea. If the foreign body sensation persists, remove the lens, rinse it with a recommended rinsing solution, and re-insert. If the foreign body sensation still persists, remove the lens and contact your eyecare practitioner.
- Check for the proper lens centration by covering your left eye. If the vision of your right eye is crisp and clear, the lens is in its proper position
- To insert your left lens, follow the same procedure.

If, after insertion of one of your lenses, the vision in that eye is blurred, check for the following:

- The lens is not centered on the eye.
- Cosmetics or oils are on the lens.
- The lens is on the wrong eye.
- The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after eliminating all of the above possibilities, remove both lenses and consult your eyecare practitioner.

CENTERING THE LENS

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To re-center a lens which has become displaced, first wash, thoroughly rinse and dry your hands, then follow one of the three procedures listed below:

- 1 Look in the direction of the displaced lens. The lens will usually slide toward the center of the eye and re-center itself on the cornea.
- 2 Close your eyelids and gently massage the lens into place through the closed lid, using your index finger.
- 3 Gently slide the displaced lens onto the cornea while the eye is open, using finger pressure on the edge of the upper or lower lid.

REMOVING THE LENS

Always remove the same lens first.

Wash, thoroughly rinse and dry your hands with a lint-free towel. Always be sure the lens is on the cornea before trying to remove it. Remove the right lens first (then the left lens), following the steps below:

- 1 With your head straight, look upward as far as you can.
- 2 Place the middle finger of your right hand (left hand if you are left-handed) on the lower eyelid of your right eye and pull the eyelid down, then touch the lower edge of the lens with the tip of your right index finger.
- 3 While still looking up, slide the lens down onto the white part of your eye with your index finger.
- 4 Still looking up, move your index finger slightly to your left and move your thumb up so that you can pinch the lens gently between your thumb and the index finger releasing the surface tension between the lens and eye. Remove the lens from the eye.

Note: In removing the lenses, be sure that you use your fingers and not your fingernails. A fingernail can injure your eye and/or tear the lens.

EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, you should: **FLUSH YOUR EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**

INSTRUCTIONS FOR THE MONOVISION WEARER

You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state driver's license requirements with monovision correction.

Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.

Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.

It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

The decision to be fit with a monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

THE WEARING SCHEDULE SHOULD BE DETERMINED BY YOUR EYECARE PRACTITIONER. Patients tend to over wear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by your eyecare practitioner, also are extremely important.

The PROCLEAR 1-DAY (*omafilcon A*) Contact Lenses are indicated for Daily Wear - less than 24 hours, while awake. The maximum suggested wearing time for these soft contact lenses is:

<u>Day</u>	<u>Hours</u>	<u>Day</u>	<u>Hours</u>	<u>Day</u>	<u>Hours</u>
1	___	6	___	11	___
2	___	7	___	12	___
3	___	8	___	13	___
4	___	9	___	14	___
5	___	10	___		

*While patients who experience discomfort and related dry eye symptoms during lens wear arising from Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only) may wear these lenses with improved comfort compared to other soft (hydrophilic) contact lenses, their wearing time may be less than it would if they did not have dry eye symptoms.

NAME AND ADDRESS OF MANUFACTURER



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