

IMPORTANT: Please read carefully and keep this information for future use.

CV 43™ CV 43™FW

(tetrafilcon A)
Hydrophilic Contact Lenses

For all CV 43 and CV 43 FW (tetrafilcon A) Hydrophilic Contact Lenses for **daily wear** use: clear and handling tint.

For all CV 43 FW (tetrafilcon A) Hydrophilic Contact Lenses for **extended wear** use: clear and handling tint.

DESCRIPTION

All spherical tetrafilcon A hydrophilic contact lenses are hemispherical shells and are available in the following dimensions:

CV 43

- Diameter: 14.0 and 14.4mm
- Base Curve: 8.3, 8.6 and 8.7mm
- Center Thickness: 0.03 to 0.28mm (varies with power)
- Powers: +6.00 to -6.50 (0.25 steps)
-6.50 to -10.00 (0.50 steps)

CV 43 FW

- Diameter: 14.4mm
- Base Curve: 8.7mm
- Center Thickness: 0.03 to 0.082mm (varies with power)
- Powers: -0.25 to -6.50 (0.25 steps)
-6.50 to -10.00 (0.50 steps)

The lens material, tetrafilcon A, is a hydrophilic random terpolymer of 2-hydroxyethyl methacrylate, N-vinyl-2-pyrrolidone and methylmethacrylate joined in a three dimensional network of terpolymer chains by divinylbenzene cross links.

Produced with a handling tint, the lens is covalently bonded with C.I. Reactive Blue 163 dye to impart a light blue tint on the lens. The handling tint increases the visibility of the lens when not worn on the eye.

The physical properties of the lens are:

- Refractive Index: 1.43
- Light Transmittance: >Approximately 90% for handling tint
- Surface Character: Hydrophilic
- Water Content: 42.5%
- Oxygen Permeability: 9.3×10^{-11} (cm²/sec)
(ml O₂/ml x mmHg) at 35°C
(Fatt method for determination of oxygen permeability)

ACTIONS

When placed on the cornea, the hydrated tetrafilcon A Hydrophilic Contact Lens acts as a refracting medium to focus light rays on the retina.

INDICATIONS (Uses)

Daily Wear: CV 43 Hydrophilic Contact Lenses are indicated for daily wear for the correction of visual acuity by not-aphakic persons with non-diseased eyes that are myopic or hyperopic.

CV 43 FW lenses are indicated for daily wear by not-aphakic persons with non-diseased eyes that are myopic. The lenses can be worn by persons who exhibit astigmatism of 2.50 diopters or less that does not interfere with visual acuity.

Extended Wear: CV 43 FW Hydrophilic Contact Lenses are indicated for extended wear from 1-7 days between removals for cleaning and disinfection, as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic. The lenses can be worn by persons who exhibit astigmatism of 2.50 diopters or less that does not interfere with visual acuity.

CONTRAINDICATIONS (Uses)

DO NOT USE tetrafilcon A Hydrophilic Contact Lenses when any of the following conditions exists:

- Acute or subacute inflammation of the anterior of the eye (between the lens and iris and the cornea).
- Any eye disease which affects the cornea or conjunctiva.
- Any active corneal infection: pus (purulent), bacterial, fungal, or viral infection.
- Insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.
- Allergy to any ingredient, such as mercury or thimerosal, in the solutions necessary for care of the lenses.
- Patient is unable to follow lens care regimen or unable to obtain assistance to do so.

WARNINGS

PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use if your lenses and lens care products. **EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION; THEREFORE, IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.**

All contact lens wearers must see their eye care practitioner as directed. If your lenses are for extended wear, your eye care practitioner may prescribe more frequent visits.

The risk of ulcerative keratitis has been shown to be greater among users of extended wear lenses than among users of daily wear lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. The risk can be reduced by carefully following directions for routine lens care, including cleaning of the lens case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens users.

PRECAUTIONS

Due to the small number of patients enrolled in clinical investigations 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 parameter, 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 corrections; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Follow the instructions below to prevent damage to your eye(s) or to your lens(es):

- Before you leave your eye care practitioner's office, be able to remove your lenses promptly or have someone else be able to remove your lenses for you.
- Always follow the recommended lens care solutions and carefully follow recommended directions.
 - Never use conventional hard contact lens solutions that are not also recommended for use with soft hydrophilic lenses.
 - Always use FRESH sterile rinsing and storage solutions.
 - Do not mix or alternate thermal (heat) and chemical (not heat) lens care systems unless indicated in the lens care system labeling.
 - Chemical disinfection solutions should not be used with heat unless the product labeling indicates the use for both chemical and heat.
 - Do not use saliva or anything other than the recommended solution to wet your lenses.
- To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying will damage the lenses. Follow the lens care directions for CARE FOR A DRIED OUT LENS if your lens surface does become dry (dehydrated).
- Always wash, rinse and dry your hands before you handle your lenses. Eye irritation may result if cosmetics, lotions, soaps, creams or deodorants come in contact with your lenses and if your lenses are contaminated by infectious or non-infectious dirt.
- Avoid using aerosol products such as hair spray while wearing your lenses. If sprays are used, keep your eyes closed until the spray has settled.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eye. The lenses absorb this dye and become discolored. Whenever your eye care practitioner does use fluorescein in your eyes, your eyes should be flushed with a normal sterile saline solution and you should wait at least one hour before replacing the lenses.
- Avoid all harmful or irritating vapors and fumes while wearing your lenses.
- Do not swim with your lenses in place.
- DO NOT WEAR YOUR LENSES DURING SLEEP UNLESS INSTRUCTED TO DO SO BY YOUR EYE CARE PRACTITIONER.
- Never use tweezers or other tools to remove your lens from the container. Pour the storage solution containing the lens into your hand.
- Do not touch the lens with your fingernails.
- Always inform your doctor (general health care practitioner) that you wear contact lenses.
- Always inform your employer that you wear contact lenses. Some jobs may require the use of eye protection equipment or may require that you do not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure good health. Check with your eye care practitioner.

ADVERSE EFFECTS (Problems and What to Do)

The following problems may occur:

- eye(s) sting, burn, or itch (irritation)
- comfort is less than when the lens was first placed on the eye
- feeling of something in the eye (foreign body, scratched area)
- excessive watering (tearing) of the eyes
- unusual eye secretions
- redness of the eyes
- reduce sharpness if vision (poor visual acuity)
- blurred vision, rainbows, or halos around objects
- sensitivity to light (photophobia)
- dry eyes

Follow the procedure outlined below if you notice any of the mentioned symptoms:

- IMMEDIATELY REMOVE THE LENSES
- If the problem continues, DO NOT put the lens back on your eye. Store it in the recommended storage solution, and IMMEDIATELY consult your eye care practitioner.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, DO NOT out the lens back on your eye. Place the lens in the storage care and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse, and disinfect the lens; then reinsert it.

When any of the above symptoms occur, a serious condition such as infection, corneal ulcer, Neovascularization, or iritis may be present. Seek **immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

FITTING

Conventional methods of fitting contact lenses apply to CooperVision's tetrafilcon A Hydrophilic Contact Lenses. For a detailed description of the fitting technique, refer to the Professional Fitting Guide. Copies are available from:

CooperVision, Inc.
Attn: Regulatory Affairs
711 North Road
Scottsville, NY 14546
1-800-341-2020
www.coopervision.com

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

WEARING SCHEDULE

Daily Wear (less than 24 hours, while awake):

THE WEARING SCHEDULE FOR TETRAFILCON A LENSES WILL BE DETERMINED BY THE EYE CARE PRACTITIONER. Patients tend to overwear the lenses initially. It is important to adhere to the initial maximum wearing schedule. Regular checkups, as determined by the eye care practitioner, are also extremely important.

Studies have not been completed to show that the **CV 43** Hydrophilic Contact lenses are safe to wear during sleep. DO NOT wear these lenses while sleeping. DO NOT wear your CV 43 lenses during sleep unless instructed to do so by the eye care practitioner.

Extended Wear (greater than 24 hours , or while asleep):

THE WEARING SCHEDULE FOR CV 43 FW WILL BE DETERMINED BY THE EYE CARE PRACTITIONER. Regular checkups, as determined by the eye care practitioner, are also extremely important.

Studies have been completed to show that these hydrophilic contact lenses are safe to wear during sleep.

CAUTION: Not every patient is able to wear the CV 43 FW Hydrophilic Contact Lenses on an extended wear basis, even if the same patient can wear a contact lens on a daily wear basis. Your eye care practitioner will determine the wearing schedule that is best for you. Clinical studies have shown that a wearer's eyes adapt readily to wearing these lenses on an extended wear basis, and that limited initial wear is not usually necessary. However, your eye care practitioner may recommend a limited wearing time.

Remember, extended wear with any CV 43 FW hydrophilic contact lens is not an endurance contest. Use good judgment. Remove, clean, and disinfect your lenses anytime you notice a change in comfort, vision, or redness of your eye(s).

THE LENS MUST BE REMOVED FOR CLEANING, RINSING AND DISINFECTING AT LEAST ONCE EVERY 7 DAYS, OR AS OFTEN AS YOUR EYE CARE PRACTITIONER RECOMMENDS.

With extended wear, there may be increased risks of eye problems such as irritation, infection, corneal thickening and corneal ulcers. Periodic checkups are therefore extremely important.

LENS CARE DIRECTIONS

Basic Instructions:

- Always wash, rinse and dry your hands before handling your contact lens.
- Use the system of lens care recommended by your eye care practitioner; either chemical (not heat) or thermal (heat). DO NOT ALTERNATE OR MIX LENS CARE SYSTEMS UNLESS INDICATED IN THE LENS CARE SYSTEM LABELING.
- Chemical disinfection solutions should not be used with heat unless the product labeling indicates use for both chemical and heat.
- If you are allergic to any ingredient, such as mercury or thimerosal in the solutions necessary to care for your lenses, do not use the solution and contact your eye care practitioner.
- Carefully read your Instructions for Wearers booklet for details. Copies are available from your eye care practitioner.
- Your lenses must be cleaned, rinsed, and disinfected each time you remove them. CLEANING is necessary to remove mucus and film from the lens surface. Rinsing removes loosened debris and residual cleaning solution. DISINFECTING is necessary to destroy harmful microorganisms.
- Clean and rinse one lens at a time. Rinse the lens **thoroughly** to remove the cleaning solution. Always clean and rinse the same lens first to avoid mix-ups. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- Always disinfect your lenses after cleaning and rinsing prior to wear. Disinfect your lenses using the system (see Lens Care Table) that your eye care practitioner has recommended. Use the correct solutions to care for your lenses.

- To store your lenses, disinfect and leave them in the closed/unopened case until ready to wear. Stored lenses should be disinfected at least once a week. If the lenses have been stored in the unopened case for more than 24 hours, disinfect immediately before wearing. Put fresh solution inside the chambers of your lens case to completely cover the lenses before disinfecting.
- After reinserting your lenses, always empty and rinse your lens storage case with fresh sterile rinsing solution and allow it to air dry. When you next use the case, refill it with fresh solution.

Lens Care Table		
The solutions listed below are recommended by CooperVision, Inc. for use with all tetrafilcon A Soft Hydrophilic Contact Lenses. Eye care practitioners may recommend alternate solutions that are appropriate to the patient's use with his or her lens.		
Purpose of Lens Care Product:	Heat (Thermal)	Chemical (Not Heat)
Clean	Piaget® Daily Cleaner	MiraFlow® Extra Strength Cleaner, Opti-Free® Daily Cleaner, Opti-Free® Express Multi-Purpose Solution, Supraclear® Daily Protein Remover, Opti-One® Multi-Purpose Solution, ReNu® Multi-Purpose Solution, Quick Care® Starting Solution, Complete® Multi-Purpose Solution, Solo-Care® Multi-Purpose Solution
Rinse	Unisol® 4 Saline Solution	Opti-Free® Express Multi-Purpose Solution, Opti-One® Multi-Purpose Solution, SoftWear® Saline, Opti-Free® Rinsing, Disinfecting & Storage Solution, ReNu® Multi-Purpose Solution, Quick Care® Finishing Solution, Complete® Multi-Purpose Solution, Solo-Care® Multi-Purpose Solution
Disinfect	Unisol® 4 Saline Solution	Opti-Free® Express Multi-Purpose Solution, Opti-One® Multi-Purpose Solution, AOSEPT® Disinfection Neutralization System, Opti-Free® Rinsing, Disinfecting & Storage Solution, ReNu® Multi-Purpose Solution, Quick Care® Finishing Solution, Complete® Multi-Purpose Solution, Solo-Care® Multi-Purpose Solution
Store	Leave in unopened case after disinfecting	Opti-Free® Express Multi-Purpose Solution, Opti-One® Multi-Purpose Solution, Opti-Free® Rinsing, Disinfecting & Storage Solution, ReNu® Multi-Purpose Solution, Quick Care® Finishing Solution, Complete® Multi-Purpose Solution, Solo-Care® Multi-Purpose Solution
Lubricate Rewet	Cierz® 2	ReNu® Rewetting Drops, Opti-Free® Rewetting Drops, Complete® Lubricating/Rewetting Drops
Enzyme	Allergan® Enzymatic Contact Lens Cleaner	ReNu® Effervescent Enzymatic Cleaner, Opti-Free® Enzymatic Cleaner, Complete® Enzymatic Cleaner

Opti-Free® and Opti-One® are registered trademarks of Alcon Laboratories, Inc. AOSEPT®, Miraflow®, Solo-Care®, SoftWear® and Quick Care are registered trademarks of CIBA Vision Corporation. ReNu® is a registered trademark of Bausch & Lomb, Inc. Complete®, Unisol® 4 and Piaget® are registered trademarks of Alcon Laboratories.

THERMAL (Heat) LENS DISINFECTION

- Prepare the empty lens storage case by filling the lens chambers with the solution which your eye care practitioner has recommended to keep the lenses wet during disinfection.
- Clean the lenses with the recommended cleaning solution and thoroughly rinse your lenses with a sterile saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with the fresh solution, completely covering the lenses.
- Tightly close the top of each chamber of the lens storage case.

- Put the lens storage case into the heat disinfection unit and follow the directions to operate the unit.
- Leave lenses in the unopened storage case until cool and you are ready to place the lenses on your eyes.
- No rinsing is necessary before insertion of your lenses unless recommended by your eye care practitioner.

Emergency (Alternate) Method for Thermal (Heat) Disinfection

If your heat disinfection unit is not available, place the tightly closed case which contains the lenses and the solution into a pan of already boiling water for at least 10 minutes (15 minutes at altitudes above 7000 feet). Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lenses. NOTE: USE OF THE HEAT DISINFECTION UNIT SHOULD BE RECOMMENDED AS SOON AS POSSIBLE.

CHEMICAL (NOT HEAT) LENS DISINFECTION (Including Hydrogen Peroxide)

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- After cleaning, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the 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.
- 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 chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh saline solution prior to placement on the eye should reduce the potential for irritation.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If your tetrafilcon A Hydrophilic Contact Lens is off your eye and exposed to air for 30 minutes or longer, it will become dry and brittle.

To rewet your lens:

- Handle the lens carefully.
- Place the lens in its storage case and SOAK the lens in the recommended rinsing and storage solution for at least one hour. Soak the lens until it returns to a soft state.
- Clean and disinfect the rewetted (rehydrated) lens using the lens care system recommend by your eye care practitioner.
- If after soaking, the lens does not become soft, DO NOT USE THE LENS, but contact your eye care practitioner.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) on the eye, apply 2-3 drops of the recommended sterile rewetting or lubricating solution. Wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, immediately consult your eye care practitioner.

DIAGNOSTIC LENS CARE

Eye care practitioner's should educate contact lens technicians concerning proper care of diagnostic lenses.

Each contact lens is sterilized in a glass vial containing a sterile buffered isotonic saline solution.

- Hands should be washed and rinsed and dried with a lint free towel.
- To ensure sterility, the vial should not be opened until immediately prior to use.
- Lenses should be surfaced cleaned and disinfected prior to re-using in a diagnostic procedure or dispensing to a patient.
- Diagnostic lenses may be disinfected by heat (thermal) or chemical (not heat). Refer to the sections titled "Heat (thermal) Lens Disinfection" or "Chemical (not heat) Lens Disinfection."
- Do not alternate or mix lens care systems.

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 THEN REMOVE THE LENSES PROMPTLY AND CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

HOW SUPPLIED

Each lens is sterilized and supplied in a glass vial containing sterile buffered isotonic saline solution. The glass vial is marked with the base curve, dioptic power, diameter, manufacturing lot number of the lens and expiration date.

DO NOT USE IF THE GLASS VIAL OR SHRINK WRAP IS DAMAGED OR BROKEN

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing tetrafilcon A contact lenses or experienced with lenses should be reported to



Attn: Product Services
711 North Road
Scottsville, NY 14546
1-800-341-2020

Part# CVPI 896-5
Rev. Date: 10/2002