

Stenfilcon A Soft (Hydrophilic) Daily Disposable Contact Lenses

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

SYMBOLS KEY:

The following symbols may appear on the label or carton.

SYMBOL	DEFINITION	REFERENCE
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner	81 FR 38911
	Caution / See Instructions for Wearers	BS EN ISO 15223-1 Table 1, Symbol 5.4.4
	Use by Date (expiration date)	BS EN ISO 15223-1 Table 1, Symbol 5.1.4
	Batch Code	BS EN ISO 15223-1 Table 1, Symbol 5.1.5
	Sterile using Steam Heat	BS EN ISO 15223-1 Table 1, Symbol 5.2.5
	Manufacturer	BS EN ISO 15223-1 Table 1, Symbol 5.1.1
	Authorized representative in the European Community	BS EN ISO 15223-1 Table 1, Symbol 5.1.2
	Do not use if package is damaged	BS EN ISO 15223-1 Table 1, Symbol 5.2.8
	Consult instructions for use / consult electronic instructions for use	BS EN ISO 15223-1 Table 1, Symbol 5.4.3
	Do not re-use	BS EN ISO 15223-1 Table 1, Symbol 5.4.2
	Date of manufacture	BS EN ISO 15223-1 Table 1, Symbol 5.1.3

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

DESCRIPTION

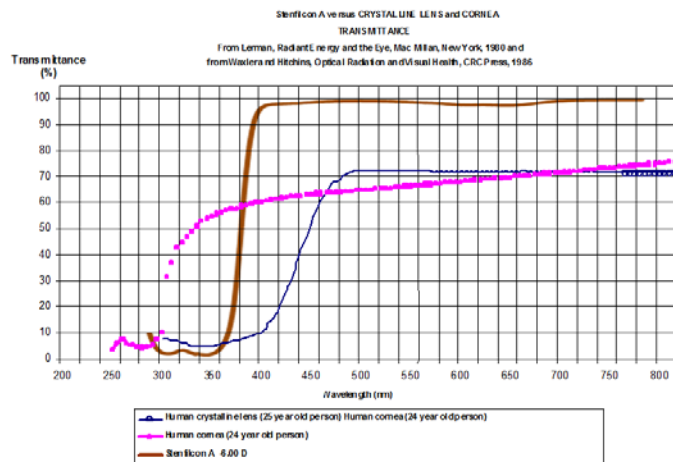
Stenfilcon A Contact Lenses are available as Asphere, Toric, Multifocal, and Multifocal Toric lens designs.

The stenfilcon A material is primarily a random copolymer of polydimethylsiloxane methacrylate and vinylmethyl acetamide. The UV blocker used is a benzotriazolyl methacrylate. The lenses have a blue tint which is added to make the lens more visible for handling. The lenses also contain a UV absorbing monomer which is used to block UV radiation.

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 UV-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.

The stenfilcon A Soft (Hydrophilic) Contact Lens (-6.00 D) blocks 86% of UVA radiation and 97% UVB radiation average across the spectrum. The radiation blockage of the stenfilcon A lens will increase for thicker lenses (please refer to accompanying transmittance curve graph).



- Lerman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p. 58, figure 2-21. Transmittance profile of the human cornea of a 24-year-old person.
- Waxler M., and V. M. Hitchins, *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p. 19, figure 5. Transmittance profile for the human crystalline lens of a 25-year-old person.

stenfilcon A contact lens parameters:

- o Chord Diameter: 13.0 mm to 15.5mm
- o Base Curve: 8.4 ± 0.5 mm and 8.7 ± 0.5 mm
- o Center Thickness: 0.08 mm to 0.218 mm (varies with power)
- o Powers: -20.00D to +20.00D
- o Cylinder Powers: -0.25D to -10.00D
- o Axis: 0° to 180° in 10° increments
- o Add Power Range: +0.50 to +4.00

The physical/optical properties of the lens are:

- o Specific Gravity 1.033
- o Refractive Index: 1.401
- o Light Transmittance: 96%
- o Surface Character: Hydrophilic
- o Water Content: 54%
- o Oxygen Permeability: 80x10⁻¹¹ [(cm²/sec)x(ml O₂)/(ml x mm Hg)]

Call our Customer Service Department at (800) 341-2020 for current availability.

ACTIONS

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

INDICATIONS FOR USE

Aspherical

Stenfilcon A ASPHERE 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

Stenfilcon A 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

Stenfilcon A 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

Stenfilcon A MULTIFOCAL TORIC Soft Contact Lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have -10.00 diopters of astigmatism or less.

CONTRAINDICATIONS (REASONS NOT TO USE):

Do not use the **stenfilcon A** 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 Eye Care 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 **stenfilcon A** 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 **stenfilcon A** 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.
- Ask the Eye Care Practitioner about wearing the 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 your 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 disposable 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.

FITTING

Conventional methods of fitting contact lenses apply to all **stenfilcon A** contact lenses. For a detailed description of the fitting techniques, refer to the **stenfilcon A** Professional Fitting and Information Guide, copies of which are available from:

CooperVision, Inc.
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com

WEARING SCHEDULE

The wearing schedule should be determined by the Eye Care Practitioner. 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.

It is recommended that all **stenfilcon A** lenses be discarded and replaced with a new lens on a daily basis.

DAILY DISPOSABLE WEAR: (less than 24 hours, while awake)

The maximum suggested wearing time is 12 hours.

LENS CARE DIRECTIONS

The **stenfilcon A 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.

For **stenfilcon A** contact lenses prescribed for daily wear single use only: The Eye Care Practitioner should review with patients that no cleaning or disinfection is needed. Patients should always dispose of lenses when they are removed and have replacement lenses or spectacles available.

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.

CARE FOR A DRIED OUT (DEHYDRATED) LENS

If any **stenfilcon A** 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, dioptric power, manufacturing lot number, and expiration date of the lens. When applicable, the blister is also labeled with the add power, cylinder power and cylinder axis.

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 observed in patients wearing any **stenfilcon A** contact lens or experienced with the lenses should be reported to:

CooperVision, Inc.
Attn: Product Services
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com