

PATIENT INSTRUCTIONS GUIDE

SILICONE HYDROGEL 1 DAY (somofilcon A)
SILICONE HYDROGEL 1 DAY TORIC (somofilcon A)
SILICONE HYDROGEL 1 DAY MULTIFOCAL (somofilcon A)
SILICONE HYDROGEL 1 DAY MULTIFOCAL TORIC (somofilcon A)

**Soft (hydrophilic) Contact Lenses for Daily Wear Single Use Only
with UV Blocker**

IMPORTANT: This Patient Guide contains important information and instructions. Please read carefully and keep this information for future use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed eyecare professional.

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INDICATIONS FOR USE

The **SILICONE HYDROGEL 1 DAY** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **SILICONE HYDROGEL 1 DAY TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The **SILICONE HYDROGEL 1 DAY MULTIFOCAL** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.

The **SILICONE HYDROGEL 1 DAY MULTIFOCAL TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and require a reading addition of +3.00 Diopters or less.

The eyecare professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfecting is required.

WEARING INFORMATION

It is essential to your safety that you read and understand the information and instructions in this booklet, and have your eyecare practitioner answer any questions, both before and after you receive contact lenses.

Your eyecare practitioner will determine your wearing schedule. After the wearing period prescribed by your eyecare practitioner, your contact lenses should be discarded and replaced with a new sterile pair. By replacing your lenses on a daily basis, lens deposits, which can affect vision and cause irritation to the eye, have little chance to build up over time as with conventional lens wear. When you discard the lens, you dispose of potential build-up problems. Your contact lenses contain a UV Blocker which is an ultraviolet (UV) radiation absorbing ingredient used to block UV radiation.

For your eye health, it is important that your contact lenses be worn only as prescribed by your eyecare practitioner. Your eyecare practitioner should be kept aware of your medical history. Adherence to your prescribed wearing schedule, and regular follow-up visits to your eyecare practitioner are also necessary for the proper and safe use of contact lenses. Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not over wear your lenses simply because they remain comfortable and you are not experiencing a problem. Only your eyecare practitioner,

through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

Ask your eyecare practitioner to explain anything that you do not understand, including any additional restrictions given to you by your eyecare practitioner.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE your contact lenses 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
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- 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, protozoal, or viral)
- If the eyes become red or irritated

WARNINGS

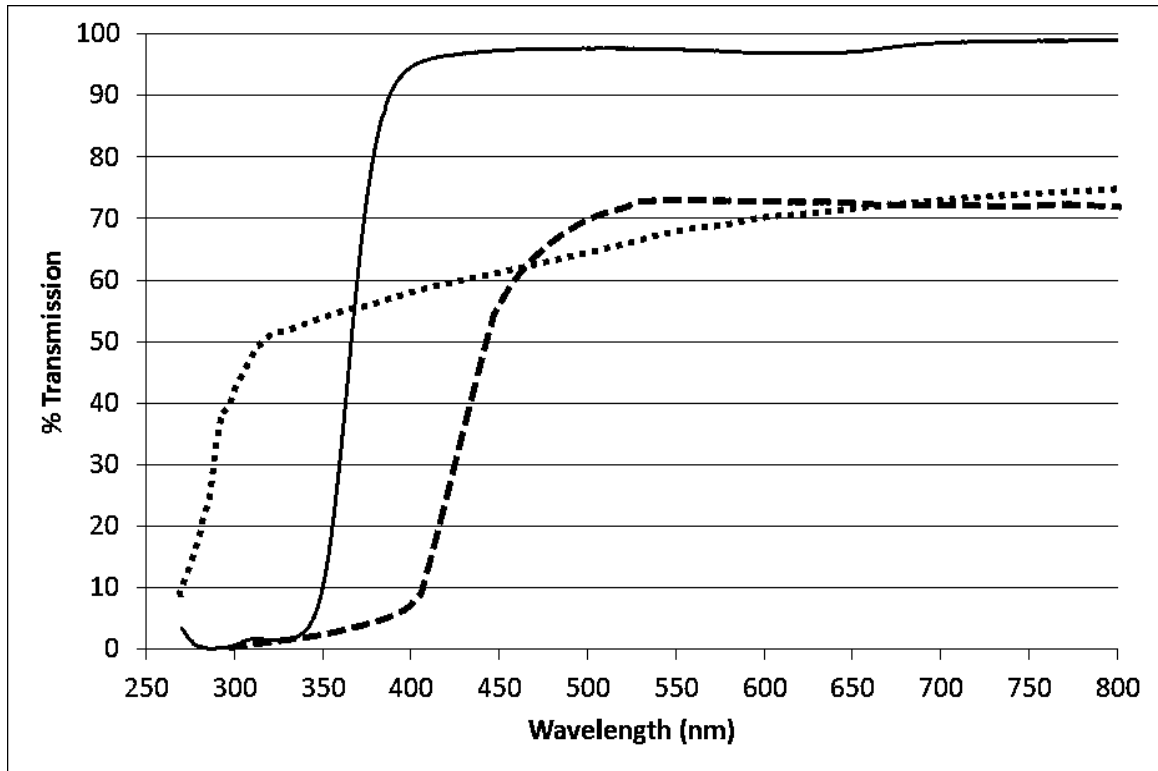
You should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses or lens care products could result in serious injury to the eye. Proper use and care of your contact lenses and lens care products, including lens cases are essential for the safe use of these products.
- Eye problems, including a sore or lesion on the cornea (corneal ulcers) can develop rapidly and lead to loss of vision.
- The risk of an infected sore or lesion on the cornea (ulcerative keratitis) is greater for people who wear extended wear contact lenses than for those who wear daily wear lenses. Do not wear your lenses while sleeping as the risk of sore or lesion on the cornea (ulcerative keratitis) is greater than among those who do not wear them while sleeping.
- The risk of ulcerative keratitis among contact lens users who smoke is greater than among non-smokers.

- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove the lenses and promptly contact your eyecare practitioner. It is recommended that you see your eyecare practitioner routinely as directed.

TRANSMITTANCE CURVES

The transmittance curve below compares SILICONE HYDROGEL 1 DAY (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker, a 24-yr. old human cornea and 25-yr. old human crystalline lens.



Key:

- Silicone Hydrogel 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker. The data shown was obtained from measurements taken through the central 3-5 mm portion for the thinnest marketed lens (-6.00DS lens with a center thickness 0.070mm).
- 24-year old human cornea¹
- 25-year old crystalline lens²

1. Lerman, S., *Radiant Energy and the Eye*, MacMillan, New York, 1980, p.58, fig. 2-21
 2. Waxler, M., Hitchins, V.M., *Optical Radiation and Visual Health*, CRC Press, Boca Raton, Florida, 1986, p.19, fig. 5

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.

Note:

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

PRECAUTIONS

At your initial visit to your eyecare practitioner:

- Be sure you read and understand the full contents of this booklet and discuss it with your eyecare practitioner.
- Give your eyecare practitioner a complete history of your eye health, including any eye injuries, diseases, conditions or other problems you have had with your eyes, even if they seem unimportant to you.
- Tell your eyecare practitioner about your general health, any medicines you are taking, current treatment by a physician, any disease you had or now have and any prior surgery.
- Before leaving the eyecare practitioner's office, you should be able to promptly remove lenses or should have someone else available who can remove the lenses.

Lens Handling Precautions:

- **Always wash and rinse your hands before handling lenses.** Do not get cosmetics, lotions, soaps, creams, deodorants or sprays in your eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-based cosmetics are less likely to cause damage to lenses than oil-based products.
- **Do not** touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- **Do not** touch the lens with your fingernails.
- **Carefully** follow the handling, insertion, removal and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- **Always** handle lenses gently and avoid dropping them.
- **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 when removing from lens blister.

Lens Wearing Precautions:

- You should remove your lenses immediately if your eyes become red or irritated.
- **Never** wear lenses beyond the period recommended by your eyecare practitioner.
- **Always** discard lenses worn as prescribed by your eyecare practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep **your eyes closed** until the spray has settled.
- **Avoid** all harmful or irritating vapors and fumes while wearing lenses.
- **Ask** your eyecare practitioner about wearing lenses during sporting activities, especially swimming and other water sports. Exposing contact lenses to water during swimming or while in a hot tub may increase the risk of eye infection from microorganisms.
- **Avoid** rubbing your eyes with the lenses on; this can irritate your eye or dislodge the lens.
- **Keep** your eyes closed tightly when washing or showering to keep water and soaps out of your eyes; these may cause loss of the senses, contamination or injury to your eyes.
- **Always** contact your eyecare practitioner before using any medicine in the eyes.
- **Ask** your eyecare practitioner whether there are any other wearing restrictions that apply to you.

Follow-up visits to your eyecare practitioner:

- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. Be sure to keep your follow-up appointments.
- When you return for follow-up visits, be sure to tell your eyecare practitioner if your eyes have felt dry, irritated or anything other than completely comfortable while wearing your contact lenses.
- If there is any question in your mind about your wearing schedule and restrictions, cleaning lens handling procedures, lens replacement program, the condition of your lenses, your follow-up visit schedule, or anything else about contact lens wear, be sure to discuss the subject with your eyecare practitioner, who is there to help you and see you use your contact lenses safely and properly.
- If your eyecare practitioner puts a dye or drops in your eyes during the examination, ask when you may reinsert the lenses. The use of most dyes or drops will require a waiting period before the lenses may be reinserted.

Who should know that you are wearing Contact Lenses?

- Inform your doctor (health care professional) about being a contact lens wearer.
- Always inform your 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.

ADVERSE REACTIONS (Problems and What to Do)

Be aware that the following problems may occur when wearing contact lenses:

- Your eyes may sting, burn and/or itch (irritation).
- There may be less comfort than when the lens was first placed on your eye.
- There may be an abnormal feeling of something in the eye (foreign body, scratched area).
- There may be potential for some temporary impairment due to peripheral infiltrates, peripheral corneal ulcers and corneal erosion. There may be potential for other physiological observations, such as local or generalized edema, corneal neovascularization, corneal staining, injection, tarsal abnormalities, iritis and conjunctivitis, some of which are clinically acceptable in low amounts.
- There may be excessive watering (tearing), unusual secretions or redness of your eyes.
- There may be poor visual acuity, blurred vision, rainbows, or halos around objects, sensitivity to light (photophobia) or dry eyes may also occur if your lenses are worn continuously or for too long a time.

If you notice any of the above symptoms:

- **Immediately remove the 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. You should discard the lens and insert a new fresh lens on your eye.
- If your lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, you should dispose of the lens and insert a new fresh lens.
- If the problem continues, you should not put the lens back on your eye but immediately consult your eyecare professional.
- 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.

LENS APPLICATION AND REMOVAL

- Your hands must be washed, rinsed and thoroughly dried with a lint free towel before handling the lenses.
- Avoid the use of cosmetics, lotions, soaps and creams before handling your lenses since eye irritation or infection may result.
- Always handle the same lens, the right or the left, first in order to avoid mix-ups.

Lens Application

- After you remove the lens from the lens package:
 1. Examine the lens to be sure it is moist, clean, clear and free of any nicks or tears.
 2. Make sure the lens is not turned inside out. Simply inspect the lens to see if the edges turn out. If they do, the lens is inside out. Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly:
 - Less than usual comfort
 - The lens folds on the eye
 - Excessive lens movement on blink
 - Blurred vision

Technique for applying your lenses:

One Hand Technique: Place the lens on your index finger. Keeping your head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment: the lens will center itself on your eye.

Two Hand Technique: With the lens on your index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of your placement hand to pull down the lower lid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.

If the lens feels uncomfortable, look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will re-center itself.

If after placement of the lens, your vision is blurred, check the following:

- a) Cosmetics or oils on the lens. Clean, rinse, disinfect and place on the eye again.
- b) The lens is on the wrong eye.
- c) The lens is inside-out (it would also not be as comfortable as normal).

If the lens still feels uncomfortable, **IMMEDIATELY REMOVE YOUR LENSES AND CONTACT YOUR EYECARE PRACTITIONER.**

Lens Removal

Your hands must be washed, rinsed and thoroughly dried with a lint free towel before removing your lenses.

CAUTION: Always be sure that the lens is in the correct position on your eye before you try to remove it (a sample check of your vision, closing one eye at a time, will tell you if the lens is in the correct position).

Look up and slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Slide the lens down to the lower white part of your eye. Squeeze the lens lightly between the thumb and the index finger. Avoid sticking the edges of the lens together.

Discard the worn lenses.

LENS CARE DIRECTIONS

1. Basic Lens Care Instructions

Eyecare practitioners should review lens care directions with you, including basic lens care information.

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, rinse and dry your hands before handling contact lenses.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in your mouth.
- Never rinse your lenses in water from the tap. There are two reasons for this:
 - a. Tap water may contain impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
 - b. You might lose your lens down the drain.

For Single Use Daily Wear

Remember there is no cleaning or disinfection needed with SILICONE HYDROGEL 1 DAY (somofilcon A) contact lenses prescribed for daily wear single use wear only. The lenses are to be discarded upon removal and have replacement lenses or spectacles available.

2. Care for a Sticking (Non-Moving) Lens

If the lens stops moving or cannot be removed, you should be instructed to apply a few drops of the recommended lubricating solution directly to your eye and wait until the lens begins to move freely on your eye before removing it. If non-movement of the lens continues, you should immediately consult your eyecare practitioner.

3. Care for a Dehydrated Lens

If a soft, hydrophilic lens is exposed to air while off the eye; it may become dry and brittle. If this happens, dispose of the lens and use a fresh one.

4. Emergencies

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

INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that 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 a 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 for 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 practitioners 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 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 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.

WEARING AND APPOINTMENT SCHEDULE

Your eyecare practitioner should prescribe the lenses for daily wear single use only. Your eyecare practitioner will determine your wearing schedule.

The maximum suggested daily wearing time for the lenses is:

Day	Hours
1	(4)
2	(5)
3	(6)
4	(7)
5	(8)
6	(9)
7	(10)
8	(11)
9	(12)
10 and after – all waking hours	

Follow-up examinations are necessary to ensure continued successful contact lens wear and to ascertain the effects of the lenses on the eyes. The following appointment schedule is a suggested guideline:

- 24 hours post-dispensing
- 7 days
- 1 month
- 3 months
- Every 6 months thereafter

NAME AND ADDRESS OF MANUFACTURER

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