Package Insert for Precision7™, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric (serafilcon A) Soft Contact Lenses

℞ only

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.

This package insert is effective as of *<insert Month, year>* and applicable to the **serafilcon A** contact lenses described below. Please read carefully and keep this information for future use.

This package insert is intended for the eye care professional but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. Alcon makes available a patient instruction booklet which is recommended to be given to patients.

PRODUCT DESCRIPTION

Precision7™, Precision7™ for Astigmatism, Precision7™ Multifocal and **Precision7™ Multifocal Toric** soft contact lenses are made from a lens material that is 55% water and 45% serafilcon A, a silicone containing hydrogel. Lenses contain the color additive Reactive Blue 247 and have a light blue-green tint that makes them easier to see when handling. Benzotriazole UV and UV-Vis absorbing monomers are used to block UV radiation and reduce transmittance of high energy visible light (HEVL) wavelengths in the range from 380 nm to 450 nm (see UV and HEVL disclaimer Notes in the ***ACTIONS*** section*).*

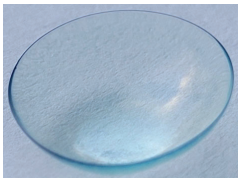


Figure 1.Photo of contact lens
(not to scale, contains reflections)

LENS PROPERTIES

- Refractive Index (hydrated): 1.40
- Light Transmittance: ≥ 90% (@ 640 nm, -3.00 D)
- UV Transmittance: τUVB <1.0 % (average percent transmittance over 280 nm to 315 nm)

  τUVA <10.0 % (average percent transmittance over 315 nm to 380 nm)
- HEVL transmittance: ≤ 80%T at 420 nm (refer to Figure 1 for transmittance profile)
- Oxygen Permeability (Dk): 119 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg), measured at 35 °C (intrinsic Dk-Polarographic method)
- Water Content: 55% by weight in normal saline

Lens Parameter Ranges

- Diameter: 13.0 to 15.0 mm
- Base Curve: 8.0 to 9.2 mm
- Spherical Power: -20.00 to +20.00 D
- Cylinder Power (toric): -0.25 to -10.00 D

- Cylinder Axis (toric): 001 to 180°
- ADD Power (multifocal): LO, MED, HI

Available Lens Parameters[1]

Precision7™ (serafilcon A) spherical contact lenses

- Chord Diameter: 14.2 mm
- Center Thickness: 0.08 mm @ -3.00 D (varies with power)
- Base Curve: 8.4 mm
- Powers: Minus: -0.25 to -8.00 D (0.25 D steps)
  -8.50 to -12.00 D (0.50 D steps)
  Plus: +0.25 to +6.00 D (0.25 D steps)
  +6.50 to +8.00 D (0.50 D steps)

Precision7™ for Astigmatism (serafilcon A) toric contact lenses

- Chord Diameter: 14.5 mm
- Center Thickness: 0.10 mm @ -3.00 D (varies with power)
- Base Curve: 8.6 mm
- Powers: Minus: plano to -10.00 D (0.25 D steps)
  Plus: +0.25 to +8.00 D (0.25 D steps)
  Cylinder: -0.75 D, -1.25 D, -1.75 D, -2.25 D. -2.75 D
- Cylinder Axes: Full circle (10° increments)

Precision7™ Multifocal (serafilcon A) contact lenses

- Chord Diameter: 14.2 mm
- Center Thickness: 0.08 mm @ -3.00 D (varies with power)
- Base Curve: 8.4 mm
- Powers: Minus: plano to -10.000 D (0.25 D steps)
  Plus: +0.25 to +6.00 D (0.25 D steps)
  ADD: LO, MED, HI

Precision7™ Multifocal Toric (serafilcon A) contact lenses

- Chord Diameter: 14.5 mm
- Center Thickness: 0.10 mm @ -3.00 D (varies with power)
- Base Curve: 8.6 mm
- Powers: Minus: plano to -10.00 D (0.25 D steps)
  Plus: +0.25 to +6.00 D (0.25 D steps)
  ADD: LO, MED, HI
  Cylinder: -0.75 D, -1.25 D, -1.75 D, -2.25 D, -2.75 D
- Cylinder Axes: Full circle (10° increments)

NOTE: Hereafter, serafilcon A spherical, toric, multifocal, and multifocal toric lenses will be referred to as serafilcon A lenses unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, serafilcon A contact lenses act as a refracting medium to focus light rays on the retina.

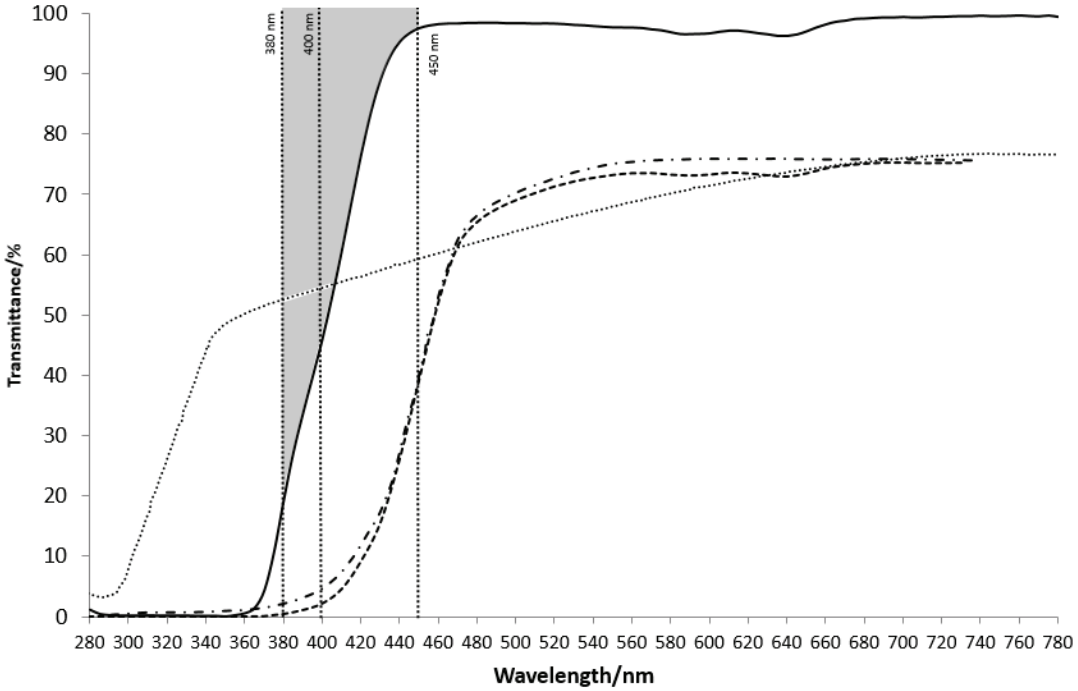
The lenses contain a UV blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. The thinnest serafilcon A lenses (-3.00 diopters) block 97% UVA radiation and 99% UVB radiation. The degree of UV radiation blockage will increase for thicker lenses.

> **WARNING**: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing goggles or sunglasses. The patient should continue to use UV-absorbing eyewear as directed.

NOTE: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time.

The lenses also contain a UV-VIS absorbing monomer to reduce high energy visible light (HEVL) reaching the back of the eye by about 34% in the range of 380 nm to 450 nm. See Figure 2 for the transmittance profile of the thinnest marketed serafilcon A lens. Radiation transmittance will be further reduced with increasing lens thickness. High energy visible light filtering by serafilcon A lenses is additive to the natural crystalline lens. There is no demonstrated clinical benefit to a 34% reduction in visible light at wavelengths below 450 nm*. The eye care professional should be consulted for more information.

Figure 2. Transmittance Curves:
Serafilcon A Contact Lens versus a Human Cornea and a Human Crystalline Lens*



Serafilcon A contact lens measured through central 6 mm portion for the thinnest marketed lens (-3.00 D, 0.080 mm).

Human Cornea from a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillian, New York, 1980, p.58, Figure 2-21.

Human crystalline lens from a 25 year old person as described in Waxler M., Hitchins V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

Combined filtering effect of the serafilcon A contact lens and the natural crystalline lens on retinal exposure.

*** NOTE:** Filtering of HEV light (HEVL) by contact lenses has not been demonstrated to confer any health benefit to the user, including but not limited to retinal protection, protection from cataract progression, reduced eye strain, improved contrast, improved acuity, reduced glare, improved low light vision, or improved circadian rhythm/sleep cycle. Consult your eye care professional for more information.

INDICATIONS (Uses)

Precision7™ (serafilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

Precision7™ for Astigmatism (serafilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have up to 6.00 diopters (D) of astigmatism.

Precision7™ Multifocal (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Precision7™ Multifocal Toric (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to 6.00 diopters (D) of astigmatism.

The lenses are to be prescribed for daily wear or extended wear for up to 6 continuous nights with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each week, or more often, if recommended by the eye care professional.

CONTRAINDICATIONS (Reasons Not To Use)

DO NOT use serafilcon A contact lenses when any of the following exists:

- Inflammation or infection of the anterior chamber of the eye
- Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- Any systemic disease that may be exacerbated by or interferes with contact lens wear
- Allergic reactions or irritation of the ocular surfaces or adnexa that may be caused by or exacerbated by the wearing of contact lenses
- Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or abnormal ocular response to contact lens wear
- If eyes become red or irritated

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear:

- Serious eye injury, scarring of the cornea, and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, emphasize to the patient the need for strict compliance with the lens care regimen including hand washing, proper lens disinfection, cleaning of the lens case, wearing restrictions, wearing schedules and follow-up visit schedules.
- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care professional if they should experience eye discomfort, foreign body sensation, excessive tearing, vision changes, and redness of the eye or other problems with their eyes.
- Non-compliance with the manufacturer's labeled lens care instructions may put the patient at significant risk of developing a serious eye infection.
- Non-sterile liquids (i.e., tap water, distilled water, homemade saline solution, or saliva) should NOT be used as a substitute for any component in the lens care process. The use of tap and distilled water

has been associated with *Acanthamoeba* keratitis, a corneal infection that is resistant to treatment and cure.
- Smoking increases the risk of corneal ulcers for contact lens users, especially when lenses are worn overnight or while sleeping.[2],[3]
- The risk of microbial keratitis (a serious eye infection) has been shown to be greater among users of extended wear lenses than among users of daily wear lenses[3]. The risk increases with the number of consecutive days that the lenses are worn between removals, even with the first overnight use.

PRECAUTIONS

To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:

Special Precautions for the Eye Care Professional:

Due to the small number of patients enrolled in the 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 professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, 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 evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.

- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in-eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Before leaving the eye care professional's office, patients should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.
- Patients who wear 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.

Eye Care Professionals should carefully instruct patients about the following safety precautions:

Handling Precautions:

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash, rinse and thoroughly dry hands with a clean lint-free towel before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Always handle lenses carefully. Never use tweezers or other sharp objects such as fingernails to remove lenses from the lens container unless specifically indicated for that use.
- Shake the blister pack gently prior to opening. Remove the lens from the blister pack by carefully pouring the lens onto the palm of your clean hand. Ensure the lens is right side out and that the correct lens for each eye is available. Inspect lenses prior to insertion. Do not insert damaged lenses.

Lens Wearing Precautions:

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the ***CARE FOR A STICKING LENS*** section. If non-movement of the lens continues, patients should be instructed to consult their eye care professional immediately.
- The eye care professional should be consulted about wearing lenses during water sports and water related activities. Exposure to water or other non-sterile liquids while wearing contact lenses in activities such as swimming, water skiing, and using hot tubs may increase the risk of ocular infection, including but not limited to *Acanthamoeba* keratitis.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion, soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses.
- Environmental dust, fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- Discard any lens that has become dehydrated or damaged. Replace with a sterile, fresh, new lens.
- Note the correct lens power for each eye to prevent getting them mixed up.
- Always keep a supply of replacement lenses on hand or have back-up spectacles available.
- Do not share lenses with anyone as this may spread microorganisms, which could result in serious eye health problems.
- Do not use lenses beyond their expiration date.

Solution Precautions:

- Eye injury due to irritation or infection may result from lens contamination. To reduce the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient (see ***LENS CARE DIRECTIONS*** section).
- Only use fresh, unexpired lens care solutions recommended for use with soft contact lenses and follow directions in the product package inserts.
- If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, the lens should be discarded and replaced with a new one to avoid possible irritation or injury to the eye. Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn.
- Do not use thermal (heat) disinfection and do not heat lens care products.
- Do not use saliva or anything other than the recommended solution for lubricating or wetting soft contact lenses.

Lens Case Precautions:

- Contact lens cases can be a source of bacterial growth and require proper use, cleaning and replacement at regular intervals as recommended by the lens case manufacturer or eye care professional.

Other Topics to Discuss with Patients:

- Periodic eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their eye care professional once each year or as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.

Who Should Know that the Patient is Wearing Contact Lenses:

- Patients should inform their health care professionals that they are wearing contact lenses.

- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

WATER ACTIVITIES

- Do not expose contact lenses to water while wearing them

Warning:

- Water can harbor microorganisms that can lead to severe infection, vision loss or blindness. If lenses have been submersed in water when showering or swimming, discard them and replace with a new pair. Ask the eye care professional for recommendations about wearing lenses during any activity involving water.

It is strongly recommended that patients be provided with a copy of the ***PATIENT INSTRUCTION BOOKLET FOR PRECISION7™, PRECISION7™ FOR ASTIGMATISM, PRECISION7™ MULTIFOCAL AND PRECISION7™ MULTIFOCAL TORIC (serafilcon A) SOFT CONTACT LENSES*** available from Alcon and understand its contents prior to dispensing the lenses.

ADVERSE EFFECTS (Possible Problems)

Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear. Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:

- Moderate to severe eye pain not relieved by removing the lens
- Foreign body sensation
- Excessive watering or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching, or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

These symptoms, if ignored, could lead to more serious complications.

WHAT TO DO IF A PROBLEM OCCURS

Patients should be instructed that if any of the above signs or symptoms is noticed, he or she should IMMEDIATELY REMOVE THE LENSES.

- **If the discomfort or problem stops,** discard the lens and replace it with a new one.
- **If the discomfort or problem continues after removing lens(es) or upon insertion of a new lens, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
    - **The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.**
- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.
- If a lens decenters on the eye, it may be possible to recenter it by:
    - Closing your eyelids and gently massaging the lens into place, or
    - Looking in the direction of the lens and blinking gently, or
    - Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.

- If a lens tears in your eye, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces do not seem to remove easily, do not pinch the eye tissue. Rinse with saline. If this does not help, contact the eye care professional for assistance.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of serafilcon A contact lenses, please notify: **Alcon, in the USA at 1-800-757-9780.**

FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to serafilcon A contact lenses. For a detailed description of the fitting techniques, refer to the ***Professional Fitting and Information Guide for Precision7™, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric (serafilcon A) Soft Contact lenses***. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099 USA

LENS WEAR & REPLACEMENT SCHEDULES

The wearing and replacement schedules should be determined by an eye care professional based on the patient's individual needs and physiological conditions. The eye care professional may recommend daily wear only or extended wear periods of up to 6 nights. Not everyone can reach the maximum wear time of 6 continuous nights.

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

- To avoid tendency of the daily wear patient to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24-hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.

Extended Wear (greater than 24 hours including while asleep):

- The eye care professional should establish an extended wear period up to 6 continuous nights that is appropriate for each patient. Once the lens is removed, the patient's eyes should have a rest period with no lens wear of overnight or longer, as recommended by the eye care professional.
- **It is suggested that new contact lens wearers first be evaluated on a daily wear schedule. If the patient is judged to be an acceptable extended wear candidate, the eye care professional may determine an extended wear schedule based upon the response of the patient**.
- See the ***WARNINGS*** section for information about the relationship between wearing schedule and corneal complications.

Lens Replacement

Lenses should be discarded and replaced with a new pair each week, or more often, if recommended by the eye care professional**.** Longer replacement periods have not been studied and are not recommended by Alcon.

LENS HANDLING INSTRUCTIONS

- Always wash and rinse hands thoroughly and dry completely with a clean, lint free towel before handling contact lenses.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
- Shake the blister pack (containing a fresh new lens) gently prior to opening.
- Remove the lens from the blister pack (or lens storage case for previously worn lenses) by carefully pouring it onto the palm of your hand.

- Ensure the lens is right side out and that you have the correct lens for each eye.
- Inspect the lenses prior to insertion.
- Do not insert damaged or unclean lenses.

Lens Insertion Instructions

- Wash and rinse hands thoroughly and dry completely with a clean, lint free towel.
- Place a lens on the tip of the clean and dry right or left index finger. Place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
- Use the fingers of the other hand to lift the upper eyelid.
- Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
- Look down and slowly release the lower lid.
- Look straight ahead and slowly release the upper lid.
- Blink gently.

Lens Removal Instructions

- Wash and rinse hands thoroughly, and dry completely with a clean, lint free towel.
- Blink fully several times.
- While looking up, use the tip of a finger to slide the lens down onto the white part of the eye.
- Remove the lens by pinching gently between thumb and forefinger. Do not pinch the eye tissue.
- If the lens is difficult to grasp, dry fingers once more and try again. Do not use rewetting drops in this instance.
- Never use tweezers, suction cups, sharp objects or fingernails to remove lenses from the lens container or eyes.

LENS CARE DIRECTIONS

Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the instructions in the package inserts provided with the lens care products recommended by the eye care professional. Failure to follow the complete regimen in accordance with manufacturer's instructions in the package inserts may contribute to problems (see the ***ADVERSE EFFECTS*** section) and/or result in the development of serious ocular complications as discussed in the ***WARNINGS*** SECTION.

Disposable Wear

- No lens care is indicated, as lenses are discarded upon removal from the eye.
- Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

Replacement Wear

- When removed between replacement periods, lenses must be cleaned and disinfected prior to reinsertion or be discarded and replaced with a fresh pair of lenses.

Basic Instructions for Lens Cleaning and Disinfection

When lenses are dispensed, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.

- The eye care professional should review the following instructions with the patient:
  - **Lenses must be cleaned, rinsed, and disinfected each time they are removed, for any reason.** If removed while the patient is away from the lens care products, the lenses may not be reinserted, but should be stored until they can be cleaned, rinsed, and disinfected.
  - **Cleaning** is necessary to remove mucus, film, and contamination from the lens surface. **Rinsing** removes all traces of the cleaner and loosened debris. **Disinfecting** is necessary to destroy remaining microorganisms.
  - Lenses must be cleaned, rinsed, disinfected, and stored in accordance with the package labeling of the lens care products recommended by the eye care professional.

- Alcon recommends a chemical (not heat) method of disinfection such as *CLEAR CARE*™ or *CLEAR CARE*™ *PLUS Cleaning & Disinfecting Solution* or *OPTI-FREE*™ *PUREMOIST*™ *Multi-Purpose Disinfecting Solution.* Typical instructions for lens care products include the steps outlined below. IMPORTANT: Hydrogen peroxide disinfecting solutions such as CLEAR CARE™ brand are not multi-purpose solutions. For hydrogen peroxide disinfection solutions, carefully follow the manufacturer's instructions.
- Soaking and Storing Your Lenses:
  - Use only fresh contact lens care solution each time you soak (store) your lenses.

  Warning:
  - Do not reuse or "top off" old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. To "top-off" means to add fresh solution to solution that has been sitting in your lens case.

- Rub and Rinse Time:
  - Some lens care products require a rub and rinse step. If so, follow the lens care manufacturer's instructions for solution quantity and rub and rinse time to reduce the risk of serious eye infections.
  - The amount of time you can store lenses before cleaning, rinsing, and disinfection steps need to be repeated will vary depending on the lens care product used.

  Warning:
  - Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.
  - Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfecting solution can lead to severe infection, vision loss or blindness.

- Discard Date for Lens Cleaning and Disinfecting Solutions
  - After opening, discard any remaining solution after the period recommended by the lens care manufacturer. *If using the lens care products listed below, discard remaining solution as follows:*
    - *CLEAR CARE™ or CLEAR CARE™ PLUS Cleaning & Disinfecting Solution - 3 months after opening.*
    - *OPTI-FREE™ PUREMOIST™ Multi-Purpose Disinfecting Solution - 6 months after opening.*

  Warning:
  - Using your lens care solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.
- Lens compatibility with an abrasive type cleaner has not been tested and is not recommended.
- Heat disinfection has not been tested and is not recommended.

Basic Instructions for the Lens Case

Contact lens care solutions and contact lens cases vary and have different purposes and instructions for use. Some cases are intended exclusively for storing contact lenses (sometimes referred to as a lens flat pack or lens storage case), while others are specially designed to contain a neutralizing disc for use with hydrogen peroxide cleaning and disinfecting systems. If not being worn on a single use basis (i.e., disposable wear), lenses must be cleaned and disinfected and then stored in the unopened case for a period of time that varies depending on the contact lens solution and lens case used. Always follow the instructions provided by the manufacturer for the lens care products used.

- The eye care professional should instruct the patient on how to use the recommended lens care solution(s) and lens case.
- Contact lens cases can be a source of bacterial growth and require proper cleaning, drying and replacement to avoid contamination or damage to lenses:
  - Clean contact lens cases with an appropriate contact lens solution and dry according to lens case instructions. Drying instructions, such as air-drying or wiping with lint-free towel, may vary depending on the lens case used.

- Replace contact lens cases at least once every 3 months, or as recommended by the lens case manufacturer.
- Replace specially designed lens cases containing a neutralizing disc according to manufacturer directions, or sooner if cleaned and disinfected lenses cause burning and stinging upon insertion.

- Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh disinfecting solution in order to avoid contamination of your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

To help avoid serious eye injury from contamination:

- Always wash, rinse and dry hands before handling the lenses.
- Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded after the time specified in the label directions.
- Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.
- Do not reuse solutions.
- Use only fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.
- Follow the manufacturer's instructions for care of the lens case.
- Replace the lens case at regular intervals to help prevent case contamination by microorganisms that can cause eye infection.
- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimen.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.
- Unless specifically indicated in the labeling, do not alternate, change, or mix lens care systems or solutions for any one pair of lenses. If in doubt as to solution suitability, consult the eye care professional.

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to remove it. It is important to wash and dry hands thoroughly before removing the lens. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline solution. Hands should be thoroughly washed and rinsed and dried with a lint-free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes lenses should be disposed of after a single use and not be re-used from patient to patient.

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 eyes immediately with tap water or fresh saline solution and immediately contact the eye care professional or visit a hospital emergency room without delay.

HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic pack containing phosphate buffered saline solution with approximately 0.2% Copolymer 845 (vinylpyrrolidone / dimethylaminoethyl methacrylate – VP/DMAEMA) and 0.015% polyoxyethylene-polyoxybutylene wetting agents and is steam sterilized.

The package is marked with variable information such as the base curve, diameter, dioptric power, cylinder power and axis (toric lenses), ADD power and MAX ADD (multifocal lenses), manufacturing lot number, date of manufacture, and expiration date.

Lenses are supplied sterile in cartons containing up to 27 individually sealed contact lenses.

DISPOSAL AND RECYCLING

Dispose of contact lenses and the blister pack lidding in the waste bin, not down the toilet or sink. The carton packaging and the polypropylene (PP) plastic shell of the blister pack should be placed in the waste bin or recycled according to local waste management guidance.

The following may appear on labels or cartons:

Symbol / Abbreviation	Description
Rx only	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
	Caution
	Consult *instructions for use* or consult *electronic instructions for use*
	Date of manufacture
	Manufacturer
	Single sterile barrier system
STERILE	Sterilized using steam
EXP	Use-by date (Expiry date)
LOT	Batch code
en	English (example of two letter code for the language)
MD	Medical device
CE	European conformity mark
EC REP	Authorized representative in the European Community/ European Union
UK CA	United Kingdom conformity mark
UDI	Unique device identifier
	Do not use if blister package is damaged
	Packaging waste license sign

Symbol / Abbreviation	Description
	DO NOT DISPOSE LENSES IN TOILET OR SINK
PWR	Power
D	Diopter (lens power)
BC	Base curve
DIA	Diameter
CYL AXIS	Cylinder power and axis
ADD	Addition power
MAX ADD	Maximum effective addition power
LO	Low
MED	Medium
HI	High

Manufacturer:
Alcon Laboratories, Inc.
6210 South Freeway
Fort Worth, TX 76134-2099, USA

www.alcon.com

U.S. Pat.: www.alconpatents.com

Part #: <*part number*>

Date: <*month, year*>

Alcon

[1] Check for actual product availability, which may change over time.
[2] Cutter, GR, Chalmers RL, Roseman M. The Clinical Presentation, Prevalence, and Risk Factors of Focal Corneal Infiltrates in Soft Contact lens Wearers. *The CLAO Journal*. Jan 1996; 22 (1): 30-37.
[3] Schein OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily-Wear and Extended-Wear Soft Contact lenses. *N Eng J Med*. 1989; 321(12):773-83.

Professional Fitting and Information Guide For

Precision7™, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric (serafilcon A) Soft Contact Lenses

For Daily Wear and Extended Wear for up to 6 Nights

Rx only

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL

Table of Contents

INTRODUCTION

Thank you for prescribing **Precision7™,, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric** (serafilcon A) soft contact lenses. The benefits of a high oxygen transmissible and wettable lens material are combined with a state of the art manufacturing process to make **Precision7™,, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric** (serafilcon A) lenses. This guide contains important information regarding fitting procedures and aftercare of the **Precision7™,, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric** (serafilcon A) contact lens patient.

PRODUCT DESCRIPTION

Precision7™,, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric soft contact lenses are made of a lens material that is approximately 55% water and 45% serafilcon A, a silicone containing hydrogel. Lenses contain the color additive Reactive Blue 247 and have a light blue-green tint that makes them easier to see when handling. Benzotriazole UV and UV-Vis absorbing monomers are used to block ultra-violet (UV) radiation in the range from 280 nm to 380 nm and reduce transmittance of high energy visible light (HEVL) wavelengths in the range from 380 nm to 450 nm (see UV and HEVL disclaimer Notes in the ***ACTIONS*** section).

- ***Lens Properties***
  - Refractive Index (hydrated): 1.40
  - Light Transmittance: ≥ 90% (@640 nm, -3.00 D)
  - UV Transmittance: τUVB <1.0 % (average percent transmittance over 280 nm to 315 nm)
    τUVA <10.0 % (average percent transmittance over 315 nm to 380 nm)
  - HEVL transmittance: ≤ 80%T at 420 nm (refer to Figure 1 for transmittance profile)
  - Oxygen Permeability (Dk): 119 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg), measured at 35 °C (intrinsic Dk - Polarographic method)
  - Water Content 55% by weight in normal saline

- ***Lens Parameter Ranges***
  - Diameter: 13.0 to 15.0 mm
  - Base Curve: 8.0 to 9.2 mm
  - Spherical Power: -20.00 to +20.00 D
  - Cylinder Power (toric): -0.25 to -10.00 D
  - Cylinder Axis (toric): 001 to 180°
  - ADD Power (multifocal): LO, MED, HI

- ***Available Lens Parameters[1]***

Precision7™ (serafilcon A) spherical contact lenses

- Chord Diameter: 14.2 mm
- Center Thickness: 0.08 mm @ -3.00 D (varies with power)
- Base Curve: 8.4 mm
- Spherical Powers: Minus: -0.25 to -8.00 D (0.25 D steps)
  -8.50 to -12.00 D (0.50 D steps)
  Plus: +0.25 to +6.00 D (0.25 D steps)
  +6.50 to +8.00 D (0.50 D steps)

Precision7™ for Astigmatism (serafilcon A) toric contact lenses

- Chord Diameter: 14.5 mm
- Center Thickness: 0.10 mm @ -3.00 D (varies with power)
- Base Curve: 8.6 mm

[1] Check for actual product availability which may change over time.

- Powers: Minus: plano to -10.00 D (0.25 steps)
  Plus: +0.25 to +8.00 D (0.25 D steps)
  Cylinder: -0.75 D, -1.25 D, -1.75 D, -2.25 D, -2.75 D
- Cylinder Axes: Full circle (10° increments)

Precision7™ Multifocal (serafilcon A) contact lenses

- Chord Diameter: 14.2 mm
- Center Thickness: 0.08 mm @ -3.00 D (varies with power)
- Base Curve: 8.4 mm
- Powers: Minus: plano to -10.00 D (0.25 steps)
  Plus: +0.25 to +6.00 D (0.25 steps)
  ADD: LO, MED, HI

Precision7™ Multifocal Toric (serafilcon A) contact lenses

- Chord Diameter: 14.5 mm
- Center Thickness: 0.10 mm @ -3.00 D (varies with power)
- Base Curve: 8.6 mm
- Powers: Minus: plano to -10.00 D (0.25 steps)
  Plus: +0.25 to +6.00 D (0.25 steps)
  ADD: LO, MED, HI
  Cylinder: -0.75 D, -1.25 D, -1.75 D, -2.25 D, -2.75 D
- Cylinder Axes: Full circle (10° increments)

NOTE: Hereafter, serafilcon A spherical, toric, multifocal and multifocal toric lenses will be referred to as serafilcon A contact lenses unless product distinction is necessary.

ACTIONS

When hydrated and placed on the cornea, serafilcon A contact lenses act as a refracting medium to focus light rays on the retina.

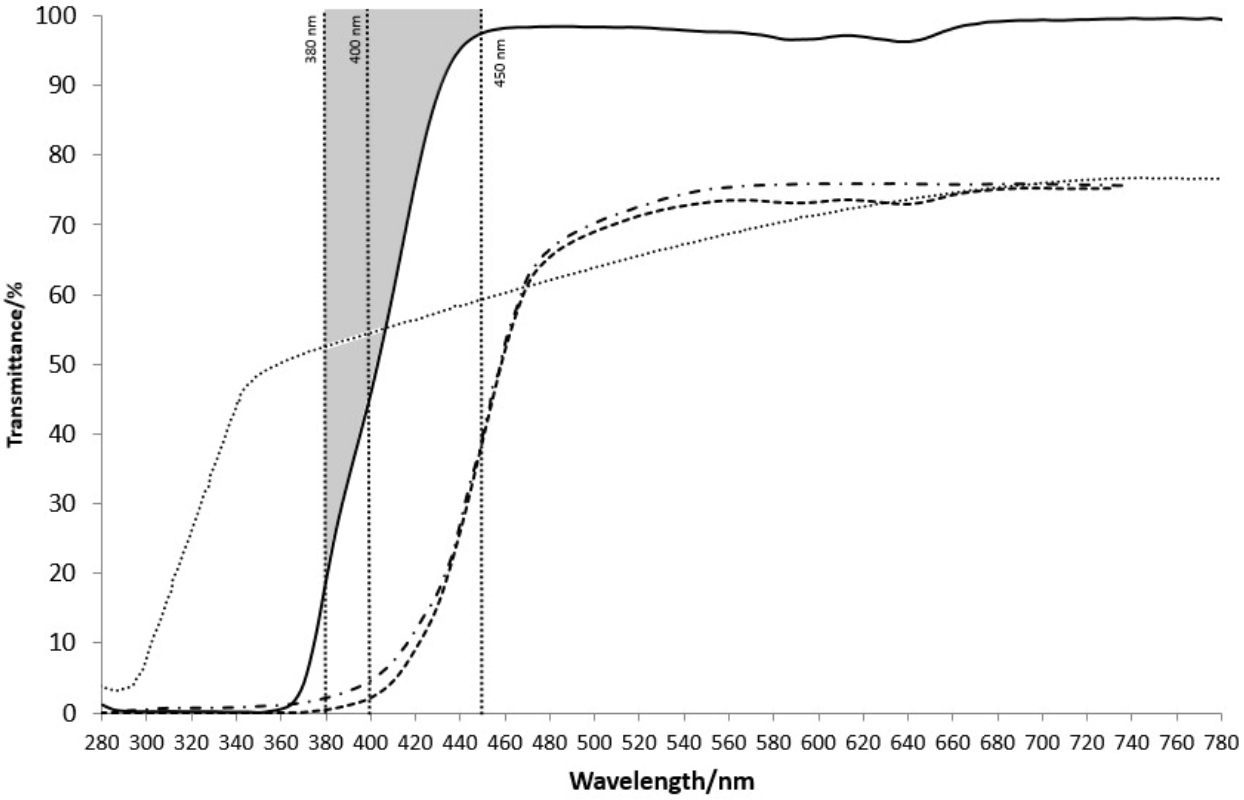
The lenses contain a UV blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. The thinnest serafilcon A lenses (-3.00 diopters) block 97% UVA radiation and 99% UVB radiation. The degree of UV radiation blockage will increase for thicker lenses.

> **WARNING**: UV absorbing contact lenses are NOT substitutes for protective UV absorbing goggles or sunglasses. The patient should continue to use UV absorbing eyewear as directed.
>
> **NOTE**: The effectiveness of wearing UV-absorbing contact lenses in preventing or reducing the incidence of ocular disorders associated with exposure to UV-light has not been established at this time.

The lenses reduce high energy visible light (HEVL) reaching the back of the eye by about 34% in the range of 380 nm to 450 nm. See Figure 1 for the transmittance profile of the thinnest marketed serafilcon A lens. Radiation transmittance will be further reduced with increasing lens thickness. High energy visible light filtering by serafilcon A soft contact lenses is additive to the natural crystalline lens. There is no demonstrated clinical benefit to a 34% reduction in visible light at wavelengths below 450 nm*. The eye care professional should be consulted for more information.

Figure 1. Transmittance Curves:

Serafilcon A Contact Lens versus a Human Cornea and a Human Crystalline Lens*



Serafilcon A contact lens measured through central 6 mm portion for the thinnest marketed lens (-3.00 D, 0.080 mm).

Human Cornea from a 24 year old person as described in Lerman, S., Radiant Energy and the Eye, MacMillian, New York, 1980, p.58, Figure 2-21.

Human crystalline lens from a 25 year old person as described in Waxler M., Hitchins V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 19, Figure 5.

Combined filtering effect of the serafilcon A contact lens and the natural crystalline lens on retinal exposure.

*** NOTE:** Filtering of HEV light (HEVL) by contact lenses has not been demonstrated to confer any health benefit to the user, including but not limited to retinal protection, protection from cataract progression, reduced eye strain, improved contrast, improved acuity, reduced glare, improved low light vision, or improved circadian rhythm/sleep cycle. Consult the eye care professional for more information.

INDICATIONS (Uses)

Precision7™ (serafilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

Precision7™ for Astigmatism (serafilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have up to 6.00 diopters (D) of astigmatism.

Precision7™ Multifocal (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Precision7™ Multifocal Toric (serafilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to 6.00 diopters (D) of astigmatism.

The lenses are to be prescribed for daily wear or extended wear for up to 6 continuous nights with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each week, or more often, if recommended by the eye care professional.

See WARNINGS for information about the relationship between wearing schedule and corneal complications.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS & ADVERSE EFFECTS

For additional important prescribing and safety information, refer to the ***PACKAGE INSERT FOR PRECISION7™, PRECISION7™ FOR ASTIGMATISM, PRECISION7™ MULTIFOCAL AND PRECISION7™ MULTIFOCAL TORIC (serafilcon A) SOFT CONTACT LENSES*** that is printed in the back of this guide.

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of **Precision7™, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric** (serafilcon A) contact lenses, please contact Alcon in the USA at **1-800-757-9780**.

FITTING GUIDELINES

Please see the appropriate sections of this booklet that contain guidelines for spherical, toric, multifocal, multifocal toric and monovision fitting techniques.

FITTING GUIDELINES (Spherical Lenses)

1. Patient Selection

The patient characteristics necessary to achieve success with **Precision7™** (serafilcon A) spherical lenses are similar to those for other spherical soft contact lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting **Precision7™** (serafilcon A) lenses. For additional tips on fitting the monovision patient refer to the section ***FITTING GUIDELINES - MONOVISION (Spherical and Toric).***

2. Pre-fitting Examination

A pre-fitting examination is necessary to:

- assess the patient's motivation, physical state and willingness to comply with instructions regarding hygiene and wearing schedule.
- make ocular measurements and assessments for initial contact lens parameter selection.
- collect baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include:

- a thorough case history.
- a sphero-cylindrical refraction.
- keratometry.
- tear film assessment.
- biomicroscopy.

3. Trial Lens Evaluation

A. Lens Base Curve Selection

A well-fitted lens provides good movement, centration and comfort. An optimal fit can be achieved for the vast majority of patients with the single 8.4 mm base curve.

B. Initial Lens Power Selection

The initial power selection should be as close as possible to the patient's prescription after taking into account spherical equivalent and vertex calculations, if necessary.

Spherical Equivalent Calculation

To determine initial lens power, convert the sphero-cylindrical spectacle Rx to its spherical equivalent as follows:

Spherical Equivalent = Sphere power + 1/2 (Cylinder Power)

Example: Spectacle Rx: -4.50 -1.00 x 180
Spherical equivalent: -4.50 + (-0.50) = -5.00

Vertex Distance Conversion

If the spherical equivalent is greater than ± 4.00 D, a vertex distance correction is necessary (see ***VERTEX DISTANCE CONVERSION CHART*** *section*) to determine the lens power required at the corneal plane.

Example: Spectacle Rx: -4.50 -1.00 x 180
Spherical equivalent: -4.50 + (-0.50) = -5.00
Vertex compensation: -4.75 (initial lens power)

C. Lens Fit Assessment

Allow the lenses to settle on the eyes for approximately 10 minutes. This allows time for the patient to adapt to the lenses and time for the lenses to equilibrate.

Evaluate the fit and movement of the lenses on the eye in primary and upward gaze positions. The **Push-up Test,** as described below, is an additional test of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-fitted Lens

A well-fitted **Precision7™** (serafilcon A) contact lens satisfies the following criteria:

1. **Good centration and full corneal coverage** in all fields of gaze
2. **Sufficient lens movement to allow tear exchange** under the lens during a blink in primary or upward gaze
3. **Satisfactory Push-up Test**
   - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
   - A well-fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
4. **Good comfort**
5. **Stable visual response** (with over-refraction)

Characteristics of a Tight (Steep) Lens Fit

A tight or steep lens fit would display some or all of the following characteristics:

1. **Insufficient or no lens movement** during a blink in primary or upward gaze
2. **Unsatisfactory Push-up Test**
   - **A tight fitting lens will resist movement.** If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
3. **Good centration**
4. **Good comfort**
5. **Fluctuating vision** between blinks

Characteristics of a Loose (Flat) Lens Fit

A loose lens fit would display some or all of the following characteristics:

1. **Reduced comfort**, usually accompanied by lower lid sensation
2. **Poor centration** with limbal exposure on exaggerated eye movement
3. **Lens edge standoff**
4. **Excessive lens movement** during the blink in primary or upward gaze
5. **Unsatisfactory Push-up Test**
   - A loose fitting lens will move easily but may remain decentered or slip under the upper lid.
6. **Vision may be blurred** after the blink

An inverted lens may mimic the characteristics of a loose lens. If any of the above signs occurs, remove the lens and check to make sure it is not inverted.

General Fitting Tips

- Trial fitting of the individual eye is strongly recommended.
- A well-fitted lens will show movement of 0.1 to 0.5 mm.

D. Final Lens Power Determination

After the characteristics of a well-fitted lens have been satisfied, conduct a **spherical over-refraction** to determine the proper lens power to be dispensed.

Example:		
	Diagnostic lens:	**-4.50 D**
	Over-refraction:	**-0.25 D**
	Final lens power:	**-4.75 D**

FITTING GUIDELINES (Toric Lenses)

The geometry of a **Precision7™ for Astigmatism** (serafilcon A) toric contact lens is a modified prism ballast design. The prism ballast design uses a toric geometry on one surface of the lens and spherical on the opposite. Stabilization is achieved by the prism at the vertical meridian on the front surface (dynamic stabilization) and with cylinder power parameters on the back surface.

To aid the fitting process, **Precision7™ for Astigmatism** (serafilcon A) contact lenses feature a scribe line on the front lens surface to enable assessment of the lens orientation. This line is at 6 o'clock approximately 1.0 mm in from the lens edge. The lens orientation finding is used for calculation of axis compensations.

1. Patient Selection

The patient characteristics necessary to achieve success with **Precision7™ for Astigmatism** (serafilcon A) lenses are similar to those for spherical lenses. A thorough pre-fitting examination should be conducted to ensure the patient is a suitable candidate for soft contact lens wear.

The following procedures should be followed when fitting **Precision7™ for Astigmatism** (serafilcon A) lenses. For additional tips on fitting the monovision patient refer to the section ***FITTING GUIDELINES -MONOVISION (Spherical and Toric)***.

2. Pre-fitting Examination

A pre-fitting examination is necessary to:

- Determine whether a patient is a suitable candidate for contact lenses in general (see ***PACKAGE INSERT: INDICATIONS*** **and** ***CONTRAINDICATIONS*** sections).
- Determine whether a patient is astigmatic to a degree requiring a toric visual correction.
- Make ocular measurements for initial contact lens parameter selection.
- Collect baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include:

- A thorough case history.
- A sphero-cylindrical refraction.
- Keratometry.
- Tear assessment.
- Biomicroscopy.

3. Fitting Methods

The following method is recommended for fitting **Precision7™ for Astigmatism** (serafilcon A) soft contact lenses to maximize success. This method allows for an extended trial period outside the office, which will help the eye care professional to minimize chair time, reduce trial lens usage, as well as increase the accuracy of final lens orientation and the final multipack prescription.

Trial Period Method

a) Make initial base curve selection if more than one available
b) Determine the appropriate sphere and cylinder powers (vertex corrected if necessary)
c) Select cylinder axis based on spectacle prescription - assume no rotation
d) Place trial lens on the eye; order trial lens if it is not in office inventory; having the correct lens allows the patient to experience good vision during the trial period
e) Evaluate fit, vision, and lens orientation
f) Dispense lens if characteristics of a **Well-fitted Lens** are satisfied
g) Reevaluate fit, vision, and lens orientation at the end of the trial period (typically a few days to a week)
h) Order multipack after fitting adjustments, if any, are made to satisfy the characteristics of a **Well-fitted Lens**

The following alternatives are offered to describe the more traditional methods of fitting lenses. While these methods are adequate to use, they can lead to an increase in chair time, trial lens usage, and multipack purchases as the fit and vision of the lenses are refined.

Empirical Method

a) Make initial base curve selection if more than one available
b) Determine the appropriate sphere and cylinder powers
c) Select the cylinder axis assuming zero rotation
d) Order multipack
e) Evaluate fit, vision, and lens orientation
f) Dispense lens if characteristics of a **Well-fitted Lens** are satisfied
g) Reorder multipacks if adjustments are made

In-Office Trial Lens Fitting Method

a) Make initial base curve selection if more than one available
b) Select diagnostic lens with similar sphere, cylinder power and axis as spectacle Rx
c) Evaluate fit, vision, over-refraction, and lens orientation
d) Order multipack if characteristics of a **Well-fitted Lens** are satisfied
e) Reorder multipack if further adjustments are necessary

NOTE: For information on fitting the monovision wearer with toric lenses, please refer to the *FITTING GUIDELINES - MONOVISION (Spherical and Toric)* section.

4. Initial Base Curve Selection

- A **Well-fitted Lens** provides **good movement, centration, and comfort** with the available *8.6 mm* base curve.

5. Initial Lens Power Selection

Spherical Lens Power

- To determine the initial lens spherical power, use the spherical component of the spectacle Rx in minus cylinder form.
- If this spherical component is greater than ± 4.00 D, a vertex distance correction is necessary. This will determine the spherical lens power required at the corneal plane.

Cylinder Lens Power

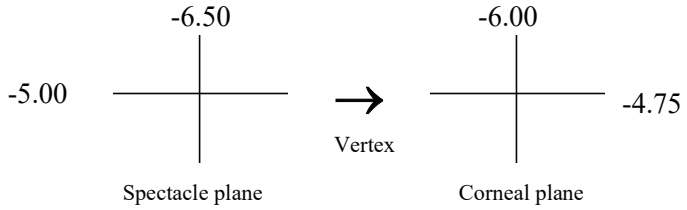
- Up to five cylinder powers may be available for **Precision7™ for Astigmatism** (serafilcon A) contact lenses.
- When available, these five powers will normally allow correction of -0.75 to -3.50 diopters of astigmatism.

Select **Precision7™ for Astigmatism** (serafilcon A) contact lens cylinder power according to the chart below:

Refraction Vertexed Cylinder Power	**Precision7™ for Astigmatism** Cylinder Power
-0.75	-0.75
-1.00	-0.75
-1.25	-1.25
-1.50	-1.25
-1.75	-1.75
-2.00	-1.75
-2.25	-2.25

-2.50	-2.25
-2.75	-2.75
-3.00	-2.75
-3.25	-2.75
-3.50	-2.75

NOTE: If the combination of sphere power and cylinder power is greater than ± 4.00 D, vertex distance compensation must be performed for each power meridian.



Example:

Spectacle Rx: **-5.00 - 1.50 x 180 (vertex distance = 12 mm)**

Corneal Plane Rx: **-4.75 -1.25 x 180**

Toric contact lens Rx: **-4.75 -1.25 x 180 (assuming no rotation)**

- When the difference between the cylinder correction at the corneal plane and the selected cylinder power to fit the patient differs by 0.50 D or more, it is necessary to make a compensation to the spherical component using the following formula:

$$\frac{\text{Corneal plane cylinder - Selected cylinder}}{2} = \text{Spherical Compensation}$$

Example:

Spectacle Rx: **-4.50 -1.50 X 180**

Corneal Plane Rx: **-4.25 -1.25 X 180**

Selected cylinder power: **-0.75**

Spherical adjustment needed: **[-1.25 - (-0.75)] / 2 = -0.25**

Toric contact lens: **-4.50 -0.75 x 180 (assuming no rotation)**

6. Lens Fit Evaluation

a) Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lenses to equilibrate with the patient's tears, replacing the buffered, isotonic saline that was in the foil pack.

b)

c) Evaluate the fit of the lenses on the eye. The **Push-up Test**, as described below is an additional test of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-fitted Lens

A well-fitted **Precision7™ for Astigmatism** (serafilcon A) contact lens satisfies the following criteria:

1. **Full corneal coverage and good centration** (no limbal exposure)
2. **Sufficient lens movement** to allow tear exchange under the lens during blink in primary or upward gaze

3. **Satisfactory Push-up Test**:
   - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
   - A **well-fitted lens** will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
4. **Good comfort**
5. **Acceptable visual acuity** with over-refraction

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep, a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. **Good centration**
2. **Insufficient or no lens movement** during a blink in primary or upward gaze
3. **Unsatisfactory Push-up Test:**
   - A **tight-fitting lens** will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
4. **Good comfort**
5. **Blurred vision** between blinks

Characteristics of a Loose (Flat) Lens Fit

If a lens fit is judged to be too flat, a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. **Decentration**
2. **Excessive lens movement** during a blink in primary or upward gaze
3. **Unsatisfactory Push-up Test:**
   - A **loose-fitting lens** will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
4. **Reduced comfort**
5. **Lens edge standoff**
6. **Blurred vision** immediately after the blink

7. Initial Lens Orientation Evaluation

A. No Rotation

When the scribe line orients at 6 o'clock, the cylinder axis of the lens that is dispensed or ordered should be the same as the spectacle refractive axis - not the trial lens axis.

Contact lens cylinder axis	**=**	**Spectacle refractive axis**

B. Clockwise Rotation

When the 6 o'clock scribe line rotates clockwise as observed looking at the patient, (i.e., temporally for the right eye, nasally for the left eye), add the degree of rotation to the spectacle refractive axis - not the trial lens axis.

Spectacle refractive axis + Trial lens rotation	**=**	**Axis to order**

Example:

Spectacle Rx:	**-2.50 -0.75 x 160**
Diagnostic Lens:	**-2.00 -0.75 x 170**

Over-refraction:	**-0.50 sphere**
Orientation:	**10 degrees clockwise (add: 160 + 10)**
Final lens to order:	**-2.50 -0.75 x 170**

C. Counterclockwise Rotation

When the 6 o'clock scribe line rotates counterclockwise, subtract the degree of rotation from the spectacle refractive axis - not the trial lens axis.

Spectacle refractive axis - Trial lens rotation	**=**	**Axis to order**

Example:

Spectacle Rx:	**-2.75 -0.75 x 180**
Diagnostic Lens:	**-2.00 -0.75 x 010**
Over-refraction:	**-0.75 sphere**
Orientation:	**10 degrees counterclockwise (subtract: 180-10)**
Final lens to order:	**-*2.75* -0.75 x 170**

NOTE: Occasionally when a cylinder axis compensation is made for orientation, the result may fall outside the traditional range of 001 to 180 degrees. If the result is a positive number, subtract 180 degrees to determine the final axis. If the result is a negative number, add 180 degrees to determine the final axis.

Example 1:

Spectacle Rx cylinder axis:	**x 170**
Orientation:	**20 degrees clockwise**
Axis calculation:	**170 + 20 = 190**
(The 190 degrees is outside the traditional axis range and is a positive number)	
Difference:	**190 - 180 = 10**
Axis to order:	**x 010**

Example 2:

Spectacle Rx cylinder axis:	**x 010**
Orientation:	**20 degrees counterclockwise**
Axis calculation:	**10 - 20 = -10**
(The -10 degrees is outside the traditional axis range and is a negative number)	
Difference:	**(-10) + 180 = 170**
Axis to order:	**x 170**

NOTE: Scribe lines on dispensed lenses must be at the same orientation as the trial lenses. Record rotation compensation as part of the final Rx.

D. Scribe Line

To view the scribe line, the following tips may be helpful:

- Scribe line is located at the 6 o'clock position.
- The first step is to narrow the slit lamp beam to approximately 0.5 mm in a horizontal orientation. Focus the beam on the lens surface at the 6 o'clock position.
- Slowly move the beam in an up and down fashion. As the beam passes near and through the scribe line it will be easy to see in direct or retro illumination.
- If the scribe line is not clearly visible, the lens may be inside out.
- Once the scribe line is located, rotate the light beam so it is parallel to the scribe line, ensure the light beam passes through the center of the pupil, and measure the amount of lens rotation.

8. Initial Visual Evaluation

The visual result is evaluated by first performing a spherical over-refraction and then measuring visual acuity. If visual acuity is acceptable, the determination of lens power required after the over-refraction will be uncomplicated.

Example:

Diagnostic lens:	**-2.00 -1.25 x 180**
Spherical Over-refraction:	**-0.50 sphere**
Final power to order:	**-2.50 -1.25 x _____***

*Determination of final cylinder axis to order will be made after compensation for lens orientation

If the spherical over-refraction does not yield acceptable vision proceed to perform a sphero-cylindrical over-refraction. For the resultant lens power to order from this over-refraction, call Alcon in the USA at 1-800-757-9780 or visit www.virtualconsultant.alcon.com.

FITTING GUIDELINES (Multifocal)

The **Precision7™ Multifocal** (serafilcon A) soft contact lens is a progressive aspheric simultaneous vision soft contact lens, intended to correct presbyopia with or without additional ametropia, available in three ADD powers [low (LO), medium (MED) and high (HI)]. For each lens, the near and intermediate powers are concentrated primarily in the central portion of the optical zone while the distance power is contained in the surrounding portion. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to + 3.00 D to see clearly at far, intermediate, and near distances.

Achieving high success with **Precision7™ Multifocal** (serafilcon A) contact lenses is dependent on several factors, including the patient's motivation, expectations and visual wearing environment, as well as your skill in optimizing the lens powers to balance binocular performance at distance and near. The information in this guide is designed to provide you with the tools to manage your presbyopic patients through each stage of the process from the initial case history to post-fitting follow-up.

1. Pre-fitting Examination

A pre-fitting examination is necessary to:

- Determine whether a patient is a suitable candidate for **Precision7™ Multifocal** (serafilcon A) contact lenses.
- Make ocular measurements and assessments for initial contact lens parameter selection.
- Collect baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include:

- A thorough case history
- Detailed assessment of patient's individual visual demands
- Understanding of patient's objectives for lens wear and expectations
- A distance sphero-cylindrical refraction, near-ADD determination and measurement of pupil diameter
- Keratometry
- Tear assessment
- Biomicroscopy

Note: The importance of a thorough case history should not be underestimated. The information gained through careful listening and probing will help greatly in satisfying each patient's unique needs.

2. Patient Selection

The eye care professional should weigh several factors when considering patient selection for an **Precision7™ Multifocal** (serafilcon A) soft contact lens fitting. When fitting a lens intended to correct for presbyopia, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers, it is important to determine the cause for discontinuation.

There are two general categories of candidates based on anticipated usage: those who seek to wear their lenses as their principal means of vision correction, and those who wish to integrate the use of their contact lenses with spectacles. The integrative user often seeks to wear their lenses for sports or other occasional activities while reverting to spectacles under poor lighting or otherwise demanding vision conditions. In general, even the part-time user does not require more than a few moments re-adaptation time following an interval of no lens wear.

While candidates with greater than 1.00 diopter of refractive error have often been thought of as better candidates than those with low error or emmetropia, this is a generalization that often does not hold true for a given individual. Success is influenced by many factors and the eye care professional is encouraged to offer **Precision7™ Multifocal** (serafilcon A) lenses to all interested presbyopic patients who satisfy the standard requirements for soft contact lens wear.

To summarize patient selection, the characteristics of "ideal candidates" and those that will be more difficult to fit are listed below:

Ideal Candidates

- Refractive cylinder ≤ 1.00 D
- Near add > 0.75 D
- Attainable visual demands that do not depend upon resolving very fine details (smaller than 20/20 letters) at *both* distance and near for extended periods while wearing **Precision7™ Multifocal** (serafilcon A) contact lenses
- Emphasis on tasks where it is advantageous to have objects simultaneously in focus over a large range of viewing distances
- Expectations consistent with actual everyday visual demands
- Motivated to wear lenses and understands that vision may not always be as sharp as with spectacles for some distances or lighting conditions

Less than Ideal Candidates

- Critical or very fine visual demands at both distance and near
- Emerging presbyope with plano or very low distance powers
- Refractive cylinder > 1.00 D (any axis) in one or both eyes or against-the-rule refractive cylinder > 0.75 D in one or both eyes
- Monocular distance acuities poorer than 20/20 with spherical equivalent refractive correction
- Myopic anisometropia where the refractive error for one of the two eyes is low (≤ 1.50 D) and has not been habitually corrected
- Pupil size larger (> 4 mm) or smaller (< 3 mm) than norm for presbyopic population under natural illumination conditions
- An abnormal binocular sensory function (e.g., amblyopia or strabismus)
- Expectation to discard and never use spectacles again, including reading glasses, even for special tasks or viewing conditions
- Highly satisfied monovision wearers
- Any other contraindications to successful contact lens wear such as tear abnormality or lid margin disease

3. Initial Lens Selection

A. Initial Base Curve Selection

Precision7™ Multifocal (serafilcon A) lenses are available in a single 8.4 mm base curve.

B. Initial Lens Power Selection

Note: A careful maximum plus sphero-cylindrical refraction and near-point ADD determination should be conducted prior to selecting a **Precision7™ Multifocal** (serafilcon A) trial lens. Auto-refraction findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.

The **Precision7™ Multifocal** (serafilcon A) lens design makes selecting the initial lens power easy. You need only manipulate the distance power. The optimum initial contact lens power, for each eye, is using the most plus or least minus vertex corrected spherical equivalent spectacle refraction and then adding a +0.25D.

C. *Initial ADD Selection*

Note: A careful near-point ADD determination should be conducted prior to selecting a **Precision7™ Multifocal** (serafilcon A) trial lens.

The **Precision7™ Multifocal** (serafilcon A 3 ADD SYSTEM allows personalized fitting for presbyopic patients. The lowest acceptable spectacle ADD is to be determined and then the table below makes initial contact lens ADD selection easy.

PRECISION7™ MULTIFOCAL ADD SELECTION

SPECTACLE ADD	BOTH EYES
Up to +1.25	LO
+1.50 to +2.00	MED
+2.25 to +2.50	HI

Example 1:	OD		OS
Spectacle Rx:	-4.50 -0.75 x 90		-4.00
Spherical equivalent (least minus):	-4.75		-4.00
Vertex corrected power:	-4.50		-3.75
Add +0.25D to vertex corrected power:	-4.25		-3.50
Spectacle Add:		+0.75	
Eye Dominance:		OD	
Initial Trial Lens:	-4.25 LO		-3.50 LO

Example 2:	OD		OS
Spectacle Rx:	+4.25 -0.25 x 180		+4.00 -0.50 x 180
Spherical equivalent (least minus):	+4.25		+3.75
Vertex corrected power:	+4.50		+3.75
Add +0.25D to vertex corrected power:	+4.75		+4.00
Spectacle Add:		+2.00	
Eye Dominance:		OS	
Initial Trial Lens:	+4.75 MED		+4.00 MED

4. Initial Lens Fitting Evaluation

a) Insert the lenses selected in Section 3 (above). If the exact power is not available, choose the next closest (least minus/most plus) lens power in your trial set.

b) Allow the lenses to settle on the eyes for approximately **5 to 10 minutes**. This allows time for the patient to adapt to the lenses and time for the lenses to equilibrate with the patient's tears.

c) Evaluate the fit of the lenses on the eye. The **Push-up Test** as described below is an important part of the lens evaluation. The following guidelines will be helpful in evaluating the physical fit of the lens:

Characteristics of a Well-fitted Lens

A well-fitted **Precision7™ Multifocal** (serafilcon A) contact lens satisfies the following criteria:

1. **Full corneal coverage and good centration** (no limbal exposure). A lens that is decentered > 1 mm, particularly temporal, is less likely to give adequate vision.
2. **Lens movement of 0.1 to 0.5 mm** should be present to allow tear exchange under the lens during a blink in primary gaze or upward gaze and to avoid variable vision.
3. **Satisfactory Push-up Test**:
   - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.
   - A well-fitted lens will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.
4. **Good comfort**.
5. **Acceptable visual acuity** with over-refraction.

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep, a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. **Good centration**
2. **Insufficient or no lens movement** during a blink in primary gaze or upward gaze
3. **Excessive conjunctival drag** (visible movement of the conjunctival vessels when the lens moves during a blink or during the push-up test)
   Note: presbyopes often have loose conjunctiva, some conjunctival movement is occasionally seen and may not be a sign of a tight fit. See **Push-up Test** below.
4. **Unsatisfactory Push-up Test:**
   - A tight fitting lens will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
5. **Good comfort**
6. **Blurred vision** between blinks

Characteristics of a Loose (Flat) Lens Fit

If a lens fit is judged to be too flat, a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. **Decentration**
2. **Excessive lens movement** during the blink in primary or upward gaze
3. **Unsatisfactory Push-up Test:**
   - A loose fitting lens will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
4. **Reduced comfort**
5. **Lens edge standoff**
6. **Blurred vision** immediately after the blink

5. Initial Lens Visual Evaluation

While lenses are settling, it is helpful to take the patient from the exam room and allow for 5-10 minutes exposure to a "real-world" setting, such as a room with an outside view. Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested at distance. If necessary, a spherical over-refraction should be performed using a trial frame or hand-held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near work activities. In addition, pupil size will not be artificially increased by the reduction in light associated with looking through the aperture of the phoropter cells, or decreased by proximal cues associated with the nearness of the instrument.

6. Fitting Procedures

Step 1. After the trial lenses have settled for at least 5 to10 minutes, measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Next, evaluate the patient's subjective impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, and cell phone). Lighting and reading distance should be what is normal for the patient.

Step 2. If distance or near vision is unsatisfactory, perform a ***distance*** over-refraction on each eye as follows. Use hand-held trial lenses and encourage plus. For example, if a plano and +0.25 D over-refraction yield the same results, use the +0.25 D endpoint. Re-check visual acuity and visual quality as described in Step 1 above. If over-refraction is other than plano, go immediately to new trial lenses, keeping ADD the same.

Step 3. If distance and near vision are satisfactory, dispense lenses and remind patient to use good lighting when reading fine print. It is helpful to let the patient experience the lenses in their natural environment before further procedures for enhancing vision are performed.

Step 4. **Enhanced Near Vision.** If near vision is unsatisfactory, determine the dominant eye by the following method. Determine the eye with **greatest plus acceptance** by placing +1.50 hand-held trial lens over each eye alternately while patient views in the distance with both eyes open. Consider the eye for which binocular vision blurs ***least*** with the +1.50 to be the non-dominant eye.

Step 4A: Check the patient's binocular acuity with +0.50 over the non-dominant eye to determine if near vision is improved and distance vision is still acceptable. If so, place a new trial lens with the same ADD on the non-dominant eye, **adjusting the distance power by +0.50.**

Enhanced near vision, Step A

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	LO	LO with additional +0.50
+1.50 to +2.00	MED	MED with additional +0.50
+2.25 to +2.50	HI	HI with additional +0.50

Next, re-check visual acuity and visual quality as described in Step 1 above. If satisfactory, dispense new distance lens power for the non-dominant eye. If near vision is still unsatisfactory, proceed to Step 4B:

Step 4B: If near vision is still unsatisfactory, adjust ADD as shown below.

Enhanced near vision, Step B		
SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	MED	MED
+1.50 to +2.00	MED	HI
+2.25 to +2.50	HI	MED

Note: It is common to question the rather non-intuitive step we suggest for enhancing vision at near in the HI ADD range, where the suggestion is to "back off" to a MED ADD for the non-dominant eye, the same suggestion we make for enhancing distance vision (below). The reason for this is that after establishing (in Step A) that increasing plus is not helpful, the next most common reason for blur at near (or distance) is unacceptable ghosting that degrades the image quality. Backing down to the MED ADD in one eye can often relieve that and actually improve vision at near.

Step 5. **Enhanced Distance Vision**. If distance over-refraction did not improve distance visual acuity or clears the distance but compromises the near vision, keep the current distance power and adjust ADD according to the chart below.

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
+1.50 to +2.00	LO	MED
+2.25 to +2.50	HI	MED

Dispensing Visit

Precision7™ Multifocal (serafilcon A) contact lenses are supplied in multipack cartons with individual foil-sealed lens containers. Locate the opening flap on the multipack carton and pull up to break the seal.

The lenses are supplied in an easy-to-open foil container designed to maintain sterility of the lens and saline storage solution. To open an individual lens container peel back the lid and carefully remove the lens from its container. Do not use tweezers or other tools to remove the lens from the package. This could damage the lens.

Conduct the following steps with each patient, even if they have previously worn contact lenses:

1. **Evaluation of Lens Fit**
   Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be re-fit with a more appropriate lens.
2. **Lens Insertion and Removal Directions**
   Instruct the patient on proper lens insertion and removal procedures. Lenses should not be dispensed to patients who are unable to insert and remove lenses.
3. **Specific Instructions for Presbyopic Patients**
   Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal contact lenses. The following information and instructions have proven useful in advising patients who wear **Precision7™ Multifocal** (serafilcon A) soft contact lenses.

a. A contact lens that contains different powers for distance and near involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves *with the eye*, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding *where* to look, these advantages may mean that the sharpness of vision may not always be exactly the same as what would be experienced with spectacles.

b. Although many individuals use **Precision7™ Multifocal** (serafilcon A) contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear spectacles, or where the disadvantages associated with spectacles are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.

c. Situations where vision with multifocal contact lenses may be less sharp or otherwise “different” than what is experienced with spectacles often involve low illumination (e.g., a semi-dark room), reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road). Patients should be instructed to make use of good lighting when reading fine print.

d. Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery until they gain some experience with the lenses in a similar visual environment.

e. Small changes in lens power can often make a significant difference in the quality of the vision experienced with multifocal contact lenses. Such changes can be best tailored to individual needs and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved are important for patient motivation during the initial period of lens wear.

FITTING GUIDELINES (Multifocal Toric)

Precision7™ Multifocal Toric (serafilcon A) lenses have a toric optic zone on the back surface, and a progressive center-near optic zone on the front surface. Orientation stability is achieved by means of a modified prism ballast design (dynamic stabilization).

To aid the fitting process, **Precision7™ Multifocal Toric** (serafilcon A) lenses feature a scribe line on the front lens surface to enable assessment of the lens orientation. The line is at the 6 o'clock position and allows for observation of lens orientation without interference from the eyelid. The lens orientation findings are then used for calculation of axis compensation.

1. Pre-fitting Examination

A pre-fitting examination is necessary to:

- determine whether a patient is a suitable candidate for contact lenses in general
- determine whether a patient is astigmatic to a degree requiring a toric visual correction
- make ocular measurements for initial contact lens parameter selection
- collect baseline clinical information to which post-fitting examination results can be compared
- determine whether or not the patient requires a reading addition

A pre-fitting examination should include:

- a thorough case history
- detailed assessment of patient´s individual vision demands
- understanding of patient's motivation and expectations
- a sphero-cylindrical refraction
- assessment of near-point ADD and pupil diameter
- keratometry
- tear assessment
- biomicroscopy

NOTE: The importance of a thorough case history should not be underestimated. The information gained through careful listening and probing will help greatly in satisfying each patient's unique needs.

2. Patient Selection

The eye care professional should weigh several factors when considering patient selection for a **Precision7™ Multifocal Toric** (serafilcon A) soft contact lens fitting. When fitting a lens intended to correct for presbyopia and astigmatism, it is especially important to evaluate the particular visual needs, objectives, lifestyle and expectations of the individual patient. Prospective candidates may include current contact lens wearers, former wearers, and persons with no previous wear history. For former wearers it is important to determine the cause for discontinuation.

There are two general categories of candidates based on anticipated usage: those who seek to wear their lenses as their principal means of vision correction, and those who wish to integrate the use of their contact lenses with spectacles. The integrative users often seek to wear their lenses for sports or other occasional activities while reverting to spectacles under poor lighting or otherwise demanding vision conditions. In general, even the part-time users do not require more than a few moments re-adaptation time following an interval of no lens wear.

While candidates with greater than 1.00 diopter of spherical refractive error have often been thought of as better candidates than those with low error or emmetropia, this is a generalization that often does not hold true for a given individual. Success is influenced by many factors and the eye care professional is encouraged to offer **Precision7™ Multifocal Toric** (serafilcon A) contact lenses to all interested presbyopic patients who satisfy the standard requirements for soft contact lens wear.

To summarize patient selection, the characteristics of "ideal candidates" and those that will be more difficult to fit are listed below:

Ideal Candidates:

- Refractive cylinder of ≥ 0.75 D in one or both eyes

- Attainable visual demands that do not depend upon resolving very fine details (smaller than 20/20 letters) at both distance and near for extended periods.
- Emphasis on tasks where it is advantageous to have objects simultaneously in focus over a large range of viewing distances
- Expectations consistent with actual everyday visual demands
- Motivated to wear contact lenses and understands that vision may not always be as sharp as with spectacles for some distances or lighting conditions
- Unable to adapt to monovision correction

Less than Ideal Candidates:

- Critical or very fine visual demands at both distance and near
  - Pupil size larger (> 4 mm) or smaller (< 3 mm) than norm for presbyopic population under natural illumination conditions
  - Myopic anisometropia where the refractive error for one of the two eyes is low (≤1.50 D) and has not been habitually corrected
  - Abnormal binocular sensory function (e.g., amblyopia or strabismus)
  - Expectation to discard and never use spectacles again, even for special tasks or viewing conditions
- Highly adapted monovision wearers with a large difference (e.g., 2.00 D) in the monovision contact lens prescription for the right and left eyes
- Contraindications to successful contact lens wear such as tear abnormality or lid margin disease

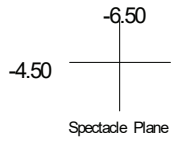
3. Initial Lens Selection

Base Curve: Precision7™ Multifocal Toric (serafilcon A) contact lenses are available in a single 8.6 mm base curve.

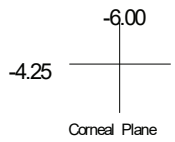
Sphere and Cylinder Power: Vertex correction

Note: A careful maximum plus sphero-cylindrical refraction and near-point ADD determination should be conducted prior to selecting an **Precision7™ Multifocal Toric** (serafilcon A) trial lens. Auto-refraction findings should be refined manually to rule out effects of instrument myopia and ensure proper control of residual accommodation.

1. Beginning with the spectacle prescription, check whether the sphere and/or cylinder power will require vertex correction for the corresponding contact lens prescription. An optical cross is a useful tool. For example, a spectacle prescription of -4.50 -2.00 x 180 would be portrayed as follows on an optical cross:



2. Compensate a given meridian for vertex if the power in the spectacle plane is ≥ 4.00 D. With a vertex distance of 12 mm, the compensated powers in this example would be:



3. The difference between the resultant powers at the two meridians is the vertex-corrected cylinder power. (6.00 D - 4.25 D = 1.75 D).

Cylinder Power

Up to 5 cylinder powers may be available for **Precision7™ Multifocal Toric** (serafilcon A) contact lenses. These 5 powers will normally allow correction of -0.75 to -3.50 diopters of astigmatism.

Select **Precision7™ Multifocal Toric** (serafilcon A) cylinder power according to the chart below:

Refraction Vertexed Cylinder Power	**Precision7™ Multifocal Toric** Cylinder Power
-0.75	-0.75
-1.00	-0.75
-1.25	-1.25
-1.50	-1.25
-1.75	-1.75
-2.00	-1.75
-2.25	-2.25
-2.50	-2.25
-2.75	-2.75
-3.00	-2.75
-3.25	-2.75
-3.50	-2.75

NOTE: If the combination of sphere power and cylinder power is greater than ± 4.00 D, vertex distance compensation must be performed for each power meridian.

- If vertex-corrected cylinder is ≤ 0.50 D, then a **Precision7™ Multifocal** (serafilcon A) multifocal (non-toric) should be ordered for this eye.
  - Find spherical equivalent (vertex-corrected sphere + ½ vertex-corrected cylinder).
  - Proceed to ***FITTING GUIDELINES (Multifocal)*** section above

When the difference between the cylinder correction at the corneal plane and the selected cylinder to fit the patient differs by 0.50 D or more, it is necessary to make a compensation to the spherical component using the following formula:

$$\frac{\text{Corneal plane cylinder - Selected cylinder}}{2} = \text{Spherical Compensation}$$

Example:

Spectacle Rx:	**-4.50 -1.50 X 180 ADD +2.00**
Corneal Plane Rx:	**-4.25 -1.25 X 180 ADD +2.00**
Selected cylinder power:	**-0.75**
Spherical adjustment needed:	**[-1.25 - (-0.75)] / 2 = -0.25**
Multifocal Toric Lens:	**-4.50 -0.75 x 180 ADD MED (assuming no rotation)**

Cylinder Axis

- Cylinder axis for **Precision7™ Multifocal Toric** (serafilcon A) contact lenses equals spectacle refraction cylinder axis rounded to the nearest 10° step.

Sphere Power

The **Precision7™ Multifocal Toric** (serafilcon A) contact lens design makes selecting the initial lens power easy. You need only manipulate the distance power. The optimum initial contact lens power, for each eye, is using the most plus or least minus vertex corrected spherical equivalent spectacle refraction and then adding a +0.25 D.

Initial ADD Selection

Note: A careful near-point ADD determination should be conducted prior to selecting an **Precision7™ Multifocal Toric** (serafilcon A) trial lens.

The **Precision7™ Multifocal Toric** (serafilcon A) 3 ADD SYSTEM allows personalized fitting for presbyopic patients. The lowest acceptable spectacle ADD is to be determined and then the table below makes initial contact lens ADD selection easy.

Precision7™ Multifocal Toric ADD selection

SPECTACLE ADD	BOTH EYES
Up to +1.25	LO
+1.50 to +2.00	MED
+2.25 to +2.50	HI

Example 1:	**OD**		**OS**
Spectacle Rx:	**-4.50 -0.75 x 90**		**-4.00D -1.25 x 90**
Vertex corrected sphere power:	**-4.25**		**-3.75**
Add +0.25D to vertex corrected power:	**-4.00**		**-3.50**
Spectacle Add:		**+0.75**	
Eye Dominance:		**OD**	
Initial Trial Lens:	**-4.00 -0.75 x 90* ADD LO**		**-3.50 -1.25 x 90* ADD LO**

Example 2:	**OD**		**OS**
Spectacle Rx:	**+4.25 -1.25 x 180**		**+4.00 D -1.50 x 160**
Vertex corrected sphere power:	**+4.50 D**		**+4.25 D**
Add +0.25D to vertex corrected power:	**+4.75**		**+4.50**
Spectacle Add:		**+2.00D**	
Eye Dominance:		**OS**	
Initial Trial Lens:	**+4.75 -1.25 x 180* ADD MED**		**+4.50 -1.25 x 160* ADD MED**

**assuming no rotation*

4. Lens Fit Evaluation (For all 3 ADD powers)

- Allow the lenses to settle on the eyes for approximately 5 to 10 minutes. This allows time for the patient to adapt to the lenses and time for the lens to equilibrate with the patient's tears, replacing the buffered, isotonic saline that was in the foil pack.
- Evaluate the fit of the lenses on the eye. The **Push-up Test**, as described below is an additional test of the lens evaluation. The following guidelines will be helpful in fit evaluation:

Characteristics of a Well-fitted Lens

A well-fitted **Precision7™ Multifocal Toric** (serafilcon A) contact lens satisfies the following criteria:

1. **Full corneal coverage and good centration** (no limbal exposure)
2. **Sufficient lens movement** to allow tear exchange under the lens during blink in primary or upward gaze
3. **Satisfactory Push-up Test**
   - This test is a reliable indicator of a good fit. With the patient looking straight ahead, place your index finger on the patient's lower lid and nudge the edge of the lens upward while observing lens movement. Then pull the lid back down and observe the return of the lens.

- A **well-fitted lens** will move freely upward, stopping shortly after passing the limbus and then return freely to its original position.

4. **Good comfort**
5. **Acceptable visual acuity** with over-refraction
6. **Clear retinoscopic reflex**

Characteristics of a Tight (Steep) Lens Fit

A tight or steep fit should not be dispensed. If a lens fit is judged to be too steep, a flatter lens (larger base curve), if available, should be evaluated. A tight or steep lens fit would display some or all of the following characteristics:

1. **Good centration**
2. **Insufficient or no lens movement** during a blink in primary or upward gaze
3. **Unsatisfactory Push-up Test**
   - A **tight fitting lens** will resist movement. If successfully nudged upward, the lens may remain decentered or return slowly to its original position.
4. **Good comfort**

Characteristics of a Loose (Flat) Lens Fit

If a lens fit is judged to be too flat, a steeper lens (smaller base curve), if available, should be evaluated. A loose lens fit would display some or all of the following characteristics:

1. **Decentration**
2. **Excessive lens movement** during a blink in primary or upward gaze
3. **Unsatisfactory Push-up Test**
   - A **loose fitting lens** will move very easily, well beyond the limbus and possibly encroaching upon or going beyond the pupil. It will then return very quickly to its original position and often times return lower than its original position.
4. **Reduced comfort**
5. **Lens edge standoff**
6. **Blurred or unstable vision**

1. Initial Lens Orientation Evaluation

A. No Rotation

When the scribe line orients at 6 o'clock, the cylinder axis of the lens that is dispensed or ordered should be the same as the spectacle refractive axis - not the trial lens axis.

Contact lens cylinder axis	**=**	**Spectacle refractive axis**

B. Clockwise Rotation

When the scribe line rotates clockwise as observed looking at the patient (i.e., temporally for the right eye, nasally for the left eye), add the degree of rotation to the spectacle refractive axis - not the trial lens axis.

Spectacle refractive axis + Trial lens rotation	**=**	**Axis to order**

Example:	
Spectacle Rx (with +0.25D added):	**-2.50 -0.75 x 160 ADD +2.00**
Diagnostic Lens:	**-2.00 -0.75 x 170 ADD MED**
Over-refraction:	**-0.50 sphere**
Orientation:	**10 degrees clockwise (add: 160 + 10)**
Final lens to order:	**-2.50 -0.75 x 170 ADD MED**

C. Counterclockwise Rotation

When the scribe line rotates counterclockwise, subtract the degree of rotation from the spectacle refractive axis - not the trial lens axis.

Spectacle refractive axis - Trial lens rotation = Axis to order

Example:	
Spectacle Rx (with +0.25D added):	**-2.75 -0.75 x 180 ADD +2.00**
Diagnostic Lens:	**-2.00 -0.75 x 010 ADD MED**
Over-refraction:	**-0.75 sphere**
Orientation:	**10 degrees counterclockwise (subtract: 180-10)**
Final lens to order:	**-2.75 -0.75 x 170 ADD MED**

NOTE: Occasionally when a cylinder axis compensation is made for orientation, the result may fall outside the traditional range of 001 to 180 degrees. If the result is a positive number, subtract 180 degrees to determine the final axis. If the result is a negative number, add 180 degrees to determine the final axis.

Example 1:	
Spectacle Rx cylinder axis:	**170**
Orientation:	**20 degrees clockwise**
Axis calculation:	**170 + 20 = 190**
(The 190 degrees is outside the traditional axis range and is a positive number)	
Difference:	**190 - 180 = 10**
Axis to order:	**010**

Example 2:	
Spectacle Rx cylinder axis:	**010**
Orientation:	**20 degrees counterclockwise**
Axis calculation:	**10 - 20 = -10**
(The -10 degrees is outside the traditional axis range and is a negative number)	
Difference:	**(-10) + 180 = 170**
Axis to order:	**170**

NOTE: Scribe line on dispensed lenses must be at the same orientation as the trial lenses. Record rotation compensation as part of the final Rx.

D. Scribe Line

To view the 6 o'clock scribe line, the following tips may be helpful:

- The first step is to narrow the slit lamp beam to approximately 0.5 mm in a horizontal orientation. Focus the beam on the lens surface at the 6 o'clock position.
- Slowly move the beam in an up and down fashion. As the beam passes near and through the scribe line, it will be easy to see in retro illumination.
- If the scribe line is not clearly visible, the lens may be inside out.

- Once the scribe line is located, rotate the light beam so it is parallel to the scribe line, ensure the light beam passes through the center of the pupil, and measure the amount of lens rotation.

2. Initial Visual Evaluation

The visual result is evaluated by first performing a spherical over-refraction and then measuring visual acuity. If visual acuity is acceptable, the determination of lens power required after the over-refraction will be uncomplicated.

Example:	
Diagnostic lens:	**-2.00 -1.25 x 180 ADD MED**
Over-refraction:	**-0.50 sphere**
Final power to order:	**-2.50 -1.25 x _____* ADD MED**

*Determination of final cylinder axis to order will be made after compensation for lens orientation.

If the spherical over-refraction does not yield acceptable vision, proceed to perform a sphero-cylindrical over-refraction. For the resultant lens power to order from this over-refraction call Alcon in the USA at 1-800-757-9780 or visit www.virtualconsultant.alcon.com.

3. Multifocal Visual Performance Evaluation

Proceed with evaluation and adjustment of lens power for presbyopic fitting only when:

- Using lenses with appropriate cylinder axis
- Lenses have been on eye a minimum of 5 to 10 minutes

NOTE: For all cylinder powers and axes, proceed as follows:

While lenses are settling, it is helpful to take the patient from the exam room and allow for 5 -10 minutes exposure to a “real-world” setting, such as a room with an outside view. Once an acceptable fit has been achieved, the visual performance of the lenses may be evaluated. Visual acuity is tested at distance. If necessary, a spherical over-refraction should be performed using a trial frame or hand-held lenses rather than a phoropter. This technique is essential when fitting multifocal lenses because it allows the patient to maintain the head posture and direction of gaze (relationship between eye and head) that he or she would naturally use during everyday tasks. This ensures that the visual performance of the lens is being assessed under conditions where the on-eye positioning matches that which will occur when the lens is being used, for example, for near-point work activities. In addition, pupil size will not be artificially increased by the reduction in light associated with looking through the aperture of the phoropter cells, or decreased by proximal cues associated with the nearness of the instrument.

4. Fitting Procedures

Step 1. After the trial lenses have settled for at least 5 to10 minutes, measure distance acuity while the patient is viewing the chart binocularly (i.e., simultaneously with both eyes). Next, evaluate the patient’s subjective impression of the near vision when trying to read typical everyday material (e.g., a newspaper, magazine, and cell phone). Lighting and reading distance should be what is normal for the patient.

Step 2. If distance or near vision is unsatisfactory, perform a distance over-refraction on each eye as follows. Use hand-held trial lenses and encourage plus. For example, if a plano and +0.25 D over-refraction yield the same results, use the +0.25 D endpoint. Re-check visual acuity and visual quality as described in Step 1 above. If over-refraction is other than plano, go immediately to new trial lenses, keeping ADD the same.

Step 3. If distance and near vision are satisfactory, dispense lenses and remind patient to use good lighting when reading fine print. It is helpful to let the patient experience the lenses in their natural environment before further procedures for enhancing vision are performed.

Step 4. Enhanced Near Vision. If near vision is unsatisfactory, determine the dominant eye by the following method. Determine the eye with greatest plus acceptance by placing a +1.50 hand-held trial lens over each eye alternately while patient views in the distance with both eyes open. Consider the eye for which binocular vision blurs least with the +1.50 to be the non-dominant eye, but keeping the cylinder power and axis the same.

Step 4A: Check the patient's binocular acuity with +0.50 over the non-dominant eye to determine if near vision is improved and distance vision is still acceptable. If so, place a new trial lens with the same ADD on the non-dominant eye, adjusting the distance power by +0.50.

Enhanced near vision, Step A

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	LO	LO with additional +0.50
+1.50 to +2.00	MED	MED with additional +0.50
+2.25 to +2.50	HI	HI with additional +0.50

Next, re-check visual acuity and visual quality as described in Step 1 above. If satisfactory, dispense new distance lens power for the non-dominant eye, keeping the cylinder and axis the same. If near vision is still unsatisfactory, proceed to Step 4B:

Step 4B: If near vision is still unsatisfactory, adjust ADD as shown below.

Enhanced near vision, Step B

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
Up to +1.25	MED	MED
+1.50 to +2.00	MED	HI
+2.25 to +2.50	HI	MED

NOTE: It is common to question the rather non-intuitive step we suggest for enhancing vision at near in the HI ADD range, where the suggestion is to "back off" to a MED ADD for the non-dominant eye, the same suggestion we make for enhancing distance vision (below). The reason for this is that after establishing (in Step 4A) that increasing plus is not helpful, the next most common reason for blur at near (or distance) is unacceptable ghosting that degrades the image quality. Backing down to the MED ADD in one eye can often relieve that and actually improve vision at near.

Step 5. Enhanced Distance Vision. If distance over-refraction or cylinder and axis compensation did not improve distance visual acuity or clears the distance but compromises the near vision, adjust ADD according to the chart below, keeping the cylinder power and axis the same.

SPECTACLE ADD	DOMINANT EYE	NON-DOMINANT EYE (PLUS ACCEPTED)
+1.50 to +2.00	LO	MED
+2.25 to +2.50	HI	MED

Dispensing Visit

Precision7™ Multifocal Toric (serafilcon A) contact lenses are supplied in multipack cartons with individual foil-sealed lens containers. Locate the opening flap on the multipack carton and pull up to break the seal.

The lenses are supplied in an easy-to-open foil container designed to maintain sterility of the lens and saline storage solution. To open an individual lens container peel back the lid and carefully remove the lens from its container. (Do not use tweezers or other tools to remove the lens from the package. This could damage the lens.)

Conduct the following steps with each patient, even if they have previously worn contact lenses:

1. **Evaluation of Lens Fit**
   Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be re-fit with a more appropriate lens.
2. **Lens Insertion and Removal Directions**
   Instruct the patient on proper lens insertion and removal procedures. Patients who are unable to place and remove lenses should not be provided with them.
3. **Specific Instructions for Presbyopic Patients**
   Specific instructions, explanations and demonstrations are important for optimizing patient success with multifocal contact lenses. The following information and instructions have proven useful in advising patients who wear **Precision7™ Multifocal Toric** (serafilcon A) soft contact lenses.

   a. A contact lens that contains different powers for distance and near involves greater technological and optical complexity than does a bifocal or multifocal spectacle lens. This is because the contact lens moves with the eye, rather than having the eye move up and down while the lens remains suspended in a frame. While the contact lens therefore gives an unobstructed field of view and greater freedom regarding where to look, these advantages may mean that the sharpness of vision may not always be exactly the same as what would be experienced with spectacles.

   b. Although many individuals use **Precision7™ Multifocal Toric** (serafilcon A) contact lenses for full-time wear, it is not unusual to find that there may be some activities where one prefers to wear spectacles, or where the disadvantages associated with spectacles are outweighed by other issues. This is an entirely normal and natural response to the challenges presented by presbyopia.

   c. Situations where vision with multifocal contact lenses may be less sharp or otherwise "different" than what is experienced with spectacles often involve low illumination (e.g., a semi-dark room), reduced visibility (e.g., outdoor conditions of fog or heavy rain), or isolated sources of very bright light (e.g., headlights of an oncoming vehicle on a narrow country road). Patients should be instructed to make use of good lighting when reading fine print.

   d. Patients should be aware that it might be advisable to refrain from wearing their lenses while driving, flying an airplane or operating heavy machinery while wearing their lenses until they gain some experience with the lenses in a similar visual environment.

   e. Small changes in lens power can often make a significant difference in the quality of the vision experienced with multifocal contact lenses. Such changes can be best tailored to individual needs and environmental conditions that the patient will personally encounter on a day-to-day basis. Confidence and assurance that such refinements, if needed, can be achieved are important for patient motivation during the initial period of lens wear.

Follow-Up Examination Procedures

- Prior to a follow-up examination, the contact lenses should be worn.
- Record patient's symptoms, if any. Particular attention should be paid to addressing any specific situations noted by the patient where further improvement of vision performance is desired.
- Measure visual acuity at distance and near with the contact lenses in place.
- Perform an over-refraction as described in the procedures for initial fitting.
- Measure orientation of the scribe line and compare to the orientation assessed at dispensing. Consider a change of the contact lens axis if a deviation of >5° is measured.

- With a biomicroscope, evaluate lens fitting characteristics and examine the lens surface for deposits.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to the initial measurements.
- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements or the “Characteristics of a Well-fitted Lens” are not satisfied during any follow-up examination, the patient should be re-fit with a more appropriate lens.

SUMMARY OF FITTING PROCEDURE

1. Carefully assess patient’s needs and expectations.
2. Assess ocular health including adequacy of the lacrimal system.
3. Perform a maximum plus sphero-cylindrical spectacle refraction and determine the spectacle ADD.
4. Select the 8.6 mm base curve trial lens.
5. Select trial lens power from the vertex corrected sphero-cylindrical refraction.
6. Start to correct the sphere and cylinder components before optimizing the near-ADD power.
7. Over-refract to maximum plus that allows good distance acuity using hand-held lenses and trial frame.
8. Assess near vision binocularly.
9. Fine tune power as necessary.
10. Verify physical fit and dispense lenses.
11. Explain lens handling and care procedures.
12. Perform first follow-up at 3-5 days following dispensing; modify power, axis and ADD if necessary based on patient’s real-world experience.

FITTING GUIDELINES - MONOVISION (Spherical and Toric)

Patient Selection

A. Monovision Needs Assessment

For a good prognosis, the patient should have adequately corrected distance and near visual acuity in each eye. Patients with reduced best-corrected visual acuity, such as the amblyopic patient, may not be a good candidate for monovision.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis), it must be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:

1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass requirements for a driver's license with monovision correction should not drive with this correction. An additional over-correction can be prescribed to improve vision.

B. Patient Education

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient must understand that monovision, as well as other presbyopic contact lenses, or other alternatives, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process, it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight-ahead and upward gaze that monovision contact lenses provide compared to spectacle bifocals.

Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following tests for selecting which eye to fit for near vs. distance vision can be used:

A) Ocular Preference Determination Methods

- Method 1 - Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.
- Method 2 - Determine which eye will accept the added power for near with the least reduction in distance vision. Place a hand-held trial near-ADD lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near-ADD lens over the right or left eye.

B) Refractive Error Method

- For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C) Visual Demands Method

- Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction (left or right), correct the eye on that side for near.

  Example:
  A person who places copy to the left side of the desk will usually function best with the near lens on the left eye.

Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Examples:

- Emmetrope: A presbyopic emmetrope who requires a +1.75 diopter ADD would have a +1.75 lens on the near eye and the other eye left without a lens.
- Bilateral myope: A presbyopic myope who requires a +1.50 diopter ADD who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.
- Unilateral astigmat:
  a) Emmetropic in one eye, astigmatic in the other

Example:	Spectacle Rx	Potential Monovision Rx
	O.D. Plano	**Uncorrected for distance**
	O.S. -0.25 -0.50 x 090	
	O.S. Spherical equivalent = -0.50	**+1.00 for near**
	Add: +1.50	

b) Myopic in one eye, astigmatic in the other

Example:	Spectacle Rx	Potential Monovision Rx
	O.D. -1.50	**Uncorrected for near**
	O.S. -2.00 -0.75 x 090	
	O.S. Spherical equivalent = -2.25	**-2.25 for distance**
	Add: +1.50	

Amblyopia

The amblyopic patient may not be a good candidate for monovision.

Astigmatism

Patients with less than 1.50 diopters of astigmatism might be successfully fit in **Precision7™** (serafilcon A) spherical contact lenses.

- Determine which eye to use for the near prescription (see Eye Selection, A-C, above)
- Add the appropriate near-ADD power to the spherical component of the astigmatic prescription for that eye.

Example:	Spectacle Rx	Potential Monovision Rx
	O.D. -2.50 -0.75 x 180	
	O.D. Spherical equivalent = -2.75	**-2.75 for distance**
	O.S. -3.00 -1.00 x 165	
	O.S Spherical equivalent = -3.50	**-2.50 for near**
	Add: +1.00	
	Dominant eye: O.D.	

If spherical contact lenses do not provide adequate vision correction due to uncorrected astigmatism, **Precision7™ for Astigmatism (serafilcon A)** toric contact lenses should be considered as an option.

Example:	Spectacle Rx	Potential Monovision Rx
	O.D.: -2.50 -0.75 x 180	**-2.50 -0.75 x 180 for distance**
	O.S.: -3.00 -1.50 x 165 **Add: +1.00** **Dominant eye: O.D.**	**-2.00 -1.25 x 160 for near (assuming no rotation)**

Near-ADD Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

Trial Lens Fitting

A trial lens fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the ***FITTING GUIDELINES (Spherical Lenses), Lens Base Curve Selection*** section described earlier in the guide.

Case history and standard clinical evaluation procedures should be used to determine the suitability of monovision. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near-ADD. With trial lenses of the proper power in place, observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reactions. Only after these vision tasks are completed, should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After evaluating the patient's performance under the above conditions, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a less favorable prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a few minutes or for several weeks. The longer these symptoms persist, the poorer the chance for successful adaptation. To help in the adaptation process, the patient can be advised to first use the lenses in a comfortable, familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it is recommended that patients be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive under optimal driving conditions. After adaptation, and success with these activities, the patient should be able to drive under other conditions with caution.

Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

- Have a third contact lens (distance power) to use when critical distance viewing is needed.
- Have a third contact lens (near power) to use when critical near viewing is needed.
- Have supplemental spectacles to wear over the monovision contact lenses for specific visual tasks. This is particularly applicable for those patients who cannot meet driver's licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in collaboration with the patient after carefully considering the patient's needs. All patients should be supplied with a copy of the ***PATIENT INSTRUCTION BOOKLET FOR PRECISION7™, PRECISION7™ FOR ASTIGMATISM, PRECISION7™ MULTIFOCAL, PRECISION7™ MULTIFOCAL TORIC (serafilcon A) SOFT CONTACT LENSES***, which contains important instructions for the monovision wearer. You can obtain copies of the instruction book by contacting an Alcon customer service representative in the USA at 1-800-241-5999**.**

DISPENSING VISIT

To help ensure patient success, the following steps should be conducted with each patient, even if they have previously worn contact lenses. Even experienced wearers are prone to develop bad habits over time.

Serafilcon A lenses are supplied sterile in foil-sealed blister pack containers. Open the blister pack by peeling back the foil lidding material and gently slide the lens out of the container with your finger or pour the lens onto the palm of your clean hand.

Conduct the following steps with each patient, even if they have previously worn contact lenses:

A. Verification of Lens Fit

Evaluate lens fit and visual response with the lens on the eye. The criteria of a well-fitted lens should be met and the patient's visual acuity should be acceptable. If not, the patient should be re-fit with a more appropriate lens.

B. Hygiene and Lens Handling Instructions

Good hygiene and proper lens handling are important factors in achieving safe, comfortable lens wear. Instruct the patient on hygiene and handling of lenses. Lenses should not be dispensed to patients who are unable to insert and remove them properly.

C. Lens Wear and Replacement Schedule (see PACKAGE INSERT)

Prescribe and explain the patient's wearing and replacement schedules.

D. Lens Care Directions (see PACKAGE INSERT)

Recommend an appropriate cleaning, rinsing, and disinfecting system and provide the patient with instructions for proper lens care, including the lens case.

E. Additional Instructions

- ***Review the PACKAGE INSERT***

  Provide the patient with all relevant information and precautions on the proper use of the lenses that are prescribed.

- ***Provide the PATIENT INSTRUCTION BOOKLET***

  Give the patient a copy of the ***PATIENT INSTRUCTION BOOKLET FOR PRECISION7™, PRECISION7™ FOR ASTIGMATISM, PRECISION7™ MULTIFOCAL AND PRECISION7™ MULTIFOCAL TORIC (serafilcon A) SOFT CONTACT LENSES***. Review the contents so the patient clearly understands the prescribed lens wear, care, and replacement schedule. You can obtain copies of the instruction book by contacting an Alcon customer service representative in the USA at 1-800-241-5999.

FOLLOW-UP EXAMINATIONS

Follow-up care is extremely important for continued successful contact lens wear and for monitoring the patient's ocular response to lens wear. Follow-up care should include:

- Case history, including questions to identify any problems related to contact lens wear.
- Management of specific problems, if any.
- A review with the patient of the lens wearing schedule, replacement schedule, and proper lens care and handling procedures.

Follow-up Examination Procedures

- Patients should be instructed to wear lenses prior to a follow-up examination. Record the patient's symptoms, if any.
- Measure visual acuity monocularly and binocularly with the contact lenses in place.
- Perform an over-refraction to check for residual refractive error.
- With a biomicroscope, evaluate lens fitting characteristics.
- Remove the lenses and conduct a thorough biomicroscopic examination with fluorescein. Rinse eyes with saline before re-inserting lenses.
- Evert upper lids to determine condition of tarsal conjunctiva.
- Periodically perform keratometry and spectacle refractions. These results should be recorded to compare to the initial measurements.

- If any observations are abnormal, use professional judgment to manage the problem and restore the eye to optimal conditions. If visual requirements are not satisfied during any follow-up examination, the patient should be re-fit with a more appropriate lens.

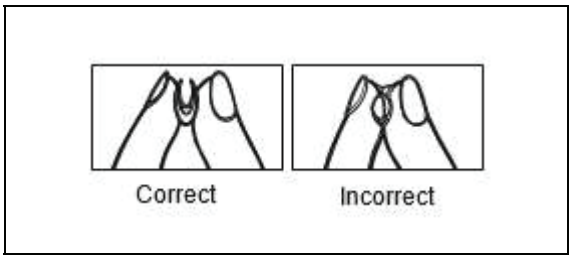
LENS HANDLING HINTS

Lens Insertion

- Wash and rinse your hands thoroughly and dry completely with a clean, lint-free towel before handling contact lenses.
- When about to place the lens on the eye, make sure the lens sits up on the placement finger. The finger should be dry so surface tension does not cause the lens to adhere to the finger.
- Check to see that the lens is right side out. A lens that is placed on the eye inside out may not feel comfortable or provide good vision.

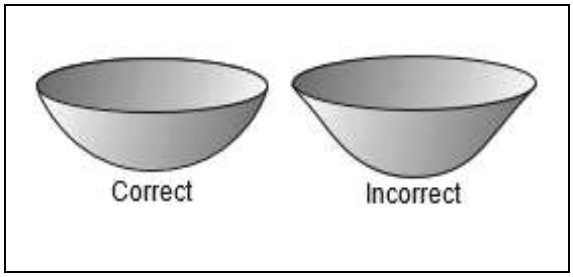
One way to do this is to perform the 'taco test' by placing the lens between your thumb and index finger and squeezing the edges together gently.

- If the edges come together, the lens is right side out.
- If the edges turn outward, the lens is wrong side out. Carefully reverse it with your fingers.



Another way is to place the lens on the tip of your index finger and check its shape.

- If the edge appears bowl-shaped, it is right side out.
- If the edge has a lip or flares outward, it is wrong side out and must be reversed.



- Place the lens directly onto the cornea (placing it on the lower sclera can lead to the lens folding after a blink). Gently roll finger away from the lens, then look down and slowly release the lower lid to help seat the lens. Look straight ahead and slowly release the upper lid. Blink gently.

Lens Removal

- **Wash hands thoroughly** with soap that does not have any oils, lotions, or perfumes.
- **Carefully dry hands** with a lint-free towel.
- It is important to remind patients to dry their hands thoroughly prior to removing their lenses. Slide the lens off the cornea (down or to the side) onto the sclera. This produces a fold in the lens, which assists in removal. With the index finger and thumb, gently pinch the lens off the eye.
- It may be easier to remove contact lenses if you use rewetting drops (approved for use with soft lenses) recommended by the eye care professional 10 to 15 minutes before lens removal. This will also help prevent lens tearing during the removal process.
- Remember to remove the same lens first (right or left), then the other lens. This helps avoid getting the lenses mixed up. Clean, rinse, and disinfect according to the lens care system being used, or discard the lenses if it is time to replace them.

Care for a Sticking Lens

- In the unlikely event that the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution (used in accordance with package labeling). The patient should wait until the lens begins to move freely on the eye before attempting to

remove it. If the lens continues to stick, the patient should **immediately** consult the eye care professional.

IN-OFFICE CARE OF TRIAL LENSES

Eye care professionals should understand the proper use of trial lenses and educate contact lens technicians accordingly.

- Each contact lens is shipped sterile in a sealed blister pack containing phosphate buffered saline solution with additives. Hands should be thoroughly washed, rinsed and dried with a lint-free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use.

- **When used as *trial lenses*, serafilcon A lenses should be disposed of after a single use and not be re-used from patient to patient.**

DISPOSAL AND RECYCLING

Dispose of contact lenses and the blister pack lidding in the waste bin, not down the toilet or sink. The carton packaging and the polypropylene (pp) plastic shell of the blister pack should be placed in the waste bin or recycled according to local waste management guidance.

ADDITIONAL INFORMATION

Alcon is pleased to assist with fitting or clinical questions regarding **Precision7™, Precision7™ for Astigmatism, Precision7™ Multifocal and Precision7™ Multifocal Toric** (serafilcon A) contact lenses. Eye care professionals having questions or problems should contact Alcon in the USA at 1-800-757-9780 or visit www.virtualconsultant.alcon.com. To order serafilcon A contact lenses contact your Alcon sales representative or call Customer Service in the USA at 1-800-241-5999.

VERTEX DISTANCE CONVERSION CHART

For minus lenses, read left to right; for plus lenses, read right to left. (12 mm Vertex Distance)

-	+	-	+	-	+	-	+
4.00	3.87	7.50	6.87	12.00	10.37	19.00	15.50
4.25	4.00	7.62	7.00	12.50	10.75	19.25	15.62
4.50	4.25	7.75	7.12	12.75	11.00	19.25	15.75
4.75	4.50	7.87	7.25	13.00	11.25	19.75	16.00
5.00	4.75	8.00	7.37	13.50	11.50	20.00	16.12
5.12	4.87	8.12	7.50	13.75	11.75	20.25	16.25
5.37	5.00	8.25	7.62	14.00	12.00	20.50	16.50
5.50	5.12	8.50	7.75	14.25	12.25	20.75	16.62
5.62	5.25	8.75	8.00	14.75	12.50	21.00	16.75
5.75	5.37	9.00	8.25	15.00	12.75	21.25	17.00
5.87	5.50	9.25	8.37	15.50	12.75	21.75	17.25
6.00	5.62	9.50	8.62	15.75	13.25	22.25	17.50
6.12	5.75	9.75	8.75	16.25	13.50	22.50	17.75
6.37	5.87	10.00	9.00	16.75	13.75	23.00	18.00
6.50	6.00	10.25	9.12	17.00	14.00	23.50	18.25
6.62	6.12	10.50	9.25	17.25	14.25	23.75	18.50
6.75	6.25	10.75	9.37	17.62	14.37	24.25	18.75
6.87	6.37	11.00	9.62	18.00	14.50	24.75	19.00
7.00	6.50	11.25	9.75	18.12	14.75	25.00	19.25
7.12	6.62	11.50	10.00	18.50	15.00	25.50	19.50
7.37	6.75	11.75	10.25	18.75	15.25	26.00	19.75

LENS CARE PRODUCT CHART FOR SOFT CONTACT LENSES

- ***CLEAR CARE™ Cleaning & Disinfecting Solution***
- ***CLEAR CARE™ PLUS Cleaning & Disinfecting Solution***
- ***OPTI-FREE™ PUREMOIST™ Contact Lens Solution***
- ***OPTI-FREE™ RepleniSH™ Contact Lens Solution***
- ***OPTI-FREE™ EXPRESS™ Contact Lens Solution***
- ***OPTI-FREE™ PureMoist™ Rewetting Drops*** >

Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099, USA

Part #: <*Insert part number*>

Date: <*Insert month, year*>