PACKAGE INSERT / FITTING GUIDE

# Bausch & Lomb SofLens® (polymacon)

# 38

## Visibility Tinted Contact Lenses

**CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed professional.

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

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## SYMBOL REFERENCE GUIDE

For label and cartons:

| | |
|---|---|
| CE 0050 | Quality System Certification Symbol |
| | Fee Paid for Waste Management |
| STERILE | Sterile Using Steam or Dry Heat |
| | See Instruction Leaflet |
| DIA $Ø_T$ | Diameter |
| EXP | Use by Date (Expiration Date) |
| LOT | Batch Code |
| PWR $(F'_V)$ | Diopter (Lens Power) |
| EC REP | Authorized Representative in European Community |
| ℞ ONLY | Caution: Federal law restricts this device to sale by or on the order of a licensed professional |
| BC | Base Curve |
| 1°C 34°F | Lower Limit of Temperature |
| YYYY-MM-DD | Effective Date |

8205900

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## IMPORTANT

This package insert and fitting guide has been developed to provide eye care professionals with information covering characteristics of the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens and to illustrate fitting procedures. It is effective as of revision date on cover and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.

This package insert and fitting guide 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 the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.



## DESCRIPTION

The Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens is a soft hydrophilic contact lens which is available as a spherical lens. The lens is made from the polymacon material, a hydrophilic polymer of 2-hydroxyethyl methacrylate, and is 38.6% water by weight when immersed in a sterile saline solution. This lens is tinted blue with up to 100 ppm of Reactive Blue Dye 246.

The physical / optical properties of the lens are:

| | |
|---|---|
| Specific Gravity: | 1.12 |
| Refractive Index: | 1.43 |
| Light Transmittance* Tinted: | C.I.E. value—approximately 86 to 98% |
| Water Content: | 38.6% |
| Oxygen Permeability: | $8.4 \times 10^{-11}$[$cm^3O_2$(STP) x cm]/ (sec x $cm^2$ x mmHg) @ 34° C (Polarographic Method) |

*CIE light transmittance will differ by average thickness across the optical zone for lenses tinted with Reactive Blue 246. For example, a lens tinted with Reactive Blue 246 having a center thickness of 0.6mm has a visible light transmittance of 86%, while a lens with a center thickness of 0.026mm has a visible light transmittance of 98%.

The SofLens® 38 (polymacon) Visibility Tinted Contact Lenses are tinted blue using Reactive Blue 246 (1,4-bis [4-(2-methacryloxyethyl) phenylamino] anthraquinone) to make the lens more visible for handling purposes. The apparent color of the SofLens® 38 (polymacon) Visibility Tinted Contact Lenses may decrease slightly following repeated disinfection. This will not affect the safety or performance of the lens.

The Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens may be prescribed for Traditional, Frequent/Planned Replacement or Disposable Wear.



## LENS PARAMETERS AVAILABLE

The Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

| | |
|---|---|
| Diameter: | 14.0mm |
| Center Thickness: | 0.035mm (-0.25D to -6.00D)<br>0.032mm to 0.026mm (-6.25D to -9.00D)<br>0.038mm to 0.094mm (plano to +4.00D) |
| Base Curve: | 8.4mm (steep), 8.7mm (medium), and 9.0mm (flat) |
| Powers (Spherical): | +4.00D to -9.00D in 0.25D steps |

## HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.



## INDICATIONS

The Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care professional. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes.

**Note:** See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

**Traditional Or Frequent/Planned Replacement Wear**

When prescribed for Traditional or Frequent/Planned Replacement Wear, the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care professional. The lens may be disinfected using either a heat or chemical disinfection system.

**Disposable Wear**

When prescribed for Disposable Wear, the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens is to be discarded after each removal.



## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa (surrounding tissue) that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

## WARNINGS

After a thorough eye examination, including appropriate medical background, patients should be fully apprised by the prescribing professional of all the risks with contact lens wear. Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care professional's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision.**
- When prescribed for Traditional or Frequent/Planned Replacement Wear, the need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule should be emphasized to the patient.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care professional.



**Extended Wear**

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants.
- While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcysts and infiltrates, and epithelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

  The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, eye care professionals views of extended wearing time vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods from 1 to 7 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.



## PRECAUTIONS

**Precautions for Eye Care Professionals**

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the prescribing eye care professional should carefully monitor the continuing ocular health of the patient and lens performance on eye.
- Eye care professionals should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye becomes red or irritated.
- Fluorescein, a yellow dye, should not be used while the lenses are on the eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used in eyes, the eyes should be flushed with sterile saline solution that is recommended for in-eye use.
- The patient should be instructed to always discard disposable lenses and lenses worn on a Frequent / Planned Replacement schedule after the recommended wearing schedule prescribed by the eye care professional.
- Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing, and eye care professionals should conduct early and frequent follow-up examination to determine ocular response to extended wear.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Eye care professionals should carefully instruct patients about the following lens care and safety precautions. It is strongly recommended that patients be provided with a copy of the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens Patient Information Booklet available from Bausch + Lomb and understand its contents prior to dispensing the lenses.



**Handling Precautions**

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be sure that before leaving the eye care professional's office, the patient is able to remove lenses promptly or have someone else available to remove them.
- Be certain that the fingers or hands are free of foreign materials before touching lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle lenses carefully and avoid dropping them.
- Do not touch the lens with fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in the Patient Information Booklet for the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens and those prescribed by the eye care professional.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.



**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.

- Always use **fresh unexpired** lens care solutions.
- Always follow directions in the package inserts for the use of contact lens solutions.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Always keep the lenses completely immersed in the recommended storage solution when lenses are not being worn (stored). Prolonged periods of drying will damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens in the Patient Information Booklet if lens surface does become dried out.
- Do not use saliva or anything other than the recommended solution for lubricating or wetting lenses.
- Tap water, distilled water or homemade saline should not be used as a substitute for any component in the lens care regimen since they have been associated with an *Acanthamoeba* keratitis infection.
- Never use conventional hard contact lens solutions that are not also recommended for use with prescribed lenses.
- Do not mix or alternate lens care systems or solutions unless indicated in the lens care system labeling.
- Do not heat the chemical disinfection solution or lenses.



**Lens Wearing Precautions**

- Never wear lenses beyond the period recommended by the eye care professional.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care professional.
- Avoid, if possible, all harmful or irritating vapors and fumes while wearing lenses.
- If aerosol products are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

**Lens Case Precautions**

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced monthly or as frequently as recommended by the lens case manufacturer or eye care professional.

**Topics to Discuss with the Patient**

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. The patient should be instructed as to a recommended follow-up schedule.
- Patients should be advised about wearing lenses during sporting and water related activities. Exposure to water while wearing contact lenses in activities such as swimming, water skiing and hot tubs may increase the risk of ocular infection including but not limited to *Acanthamoeba* keratitis.
- Always contact the eye care professional before using any medicine in the eyes.

**Who Should Know That the Patient is Wearing Contact Lenses**

- Patients should inform their doctor (health care professional) about being a contact lens wearer.
- Patients should always inform their employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you do not wear lenses.



## ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- **Immediately remove lenses**.
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. Place the lens in the storage case and contact the eye care professional. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eye care professional.**

  If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lenses and contact his or her eye care professional** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.



**Important Treatment Information for Adverse Reactions**

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

## SELECTION OF PATIENTS

Persons who require only vision correction and who would not or could not adhere to a recommended care or replacement regimen for Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lenses or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care professional must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow professional instructions are essential to their success.

A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the patient should be instructed to contact his or her eye care professional.



## FITTING PROCEDURE

**1. Pre-Fitting Examination**

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for contact lenses (consider patient hygiene and mental and physical state),
- Make ocular measurements for initial contact lens parameter selection, and
- Collect and record baseline clinical information to which postfitting examination results can be compared.

A pre-fitting examination should include spherocylinder refraction and VA, keratometry, biomicroscopic examination.

**2. Initial Lens Power & Base Curve Selection**

a. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the 8.7mm base curve lens as the initial lens, (for steeper corneas, start fitting with an 8.4mm base curve lens and; for flatter corneas, start fitting with an 9.0mm base curve) and place the lens on eye.

b. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

c. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.



**3. Initial Lens Evaluation**

a. To determine proper lens parameters, observe the lens relationship to the eye using a slit lamp.
   - Movement: The lens should provide discernible movement with:
     - Primary gaze blink
     - Upgaze blink
     - Upgaze lag
   - Centration: The lens should provide full corneal coverage.

b. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, a steeper base curve should be selected. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, then a flatter base curve should be selected.

**4. Criteria of a Well-Fitted Lens**

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed.

**5. Characteristics of a Tight (Steep) Lens**

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

**6. Characteristics of a Loose (Flat) Lens**

If the lens is too flat, it will:

- Decenter, especially on post-blink.
- Have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
- Have a tendency to be uncomfortable and irritating with fluctuating vision.
- Have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.



**7. Follow-up Care**

a. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow-up.
   - 3 or 4 days post-dispensing
   - 10 days
   - 1 month
   - 3 months
   - every six months thereafter

   At the initial follow-up evaluations the eye care professional should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

b. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

c. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

d. After the lens removal, instill sodium fluorescein (unless contraindicated) into the eyes and conduct a thorough biomicroscopy examination.
   1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
   2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
   3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

   If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.



## PROFESSIONAL FITTING SETS

Lenses must be discarded after each use.

## WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care professional. Regular checkups, as determined by the eye care professional, are extremely important.

**Daily Wear**

There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients. The wearing schedule should be determined by the eye care professional. The wearing schedule chosen by the eye care professional should be provided to the patient.

**Extended Wear (Greater than 24 hours or while asleep)**

The wearing schedule should be determined by the prescribing eye care professional for each individual patient, based upon a full examination and patient history as well as the professional's experience and professional judgement. Bausch + Lomb recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The professional should examine the patient in the early stages of extended wear to determine the corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care professional. (See the factors discussed in the Warnings section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care professional.



## MONOVISION FITTING GUIDELINES

**1. Patient Selection**

a. *Monovision Needs Assessment*

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should 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 their state driver's license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

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 should understand that monovision, as well as other presbyopic contact lenses, or other alternative, 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.



**2. Eye Selection**

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

a. *Ocular Preference Determination Methods*

Method 1—Determine which eye is the "sighting dominant 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 with the least reduction in vision. Place a trial spectacle 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 correct the eye on that side for near.

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

**3. 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.

Example:
A presbyopic emmetropic patient 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.

A presbyopic patient requiring 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.



**4. 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.

**5. Trial Lens Fitting**

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. 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 finger-nails. Again assess the reaction. As the patient continues to look around the room at both near and distant 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 the patient's performance under the above conditions is completed, 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 guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

**6. 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 a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis 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 may be recommended that the patient 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 during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.



**7. Other Suggestions**

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

- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state 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 conjunction with the patient after carefully considering the patient's needs.*

**All patients should be supplied with a copy of the SofLens® 38 (polymacon) Visibility Tinted Contact Lens Frequent/Planned Replacement Wear Patient Information Booklet or the SofLens® 38 (polymacon) Visibility Tinted Contact Lens Disposable Wear Patient Information Booklet.*



## HANDLING OF LENSES

**Patient Lens Care Directions**

When lenses are dispensed, the patient should be provided with appropriate and adequate instructions and warnings for lens care handling. The eye care professional should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system selected by the professional, the specific instructions for such products and the particular characteristics of the patient.

**Frequent/Planned Replacement Wear**

For complete information concerning the care, cleaning and disinfection of contact lenses refer to the SofLens® 38 (polymacon) Visibility Tinted Contact Lens Frequent/Planned Replacement Wear Patient Instruction Booklet.

**Disposable Wear**

For complete information concerning emergency lens care, refer to the SofLens® 38 (polymacon) Visibility Tinted Contact Lens Disposable Wear Patient Instruction Booklet.



## CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to not use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care professional if the lens does not begin to move upon blinking after several applications of the solution, and to not attempt to remove the lens except on the advice of the eye care professional.

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb SofLens® 38 (polymacon) Visibility Tinted Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

**Toll Free Telephone Number**
In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720
In Canada
1-888-459-5000

## HOW SUPPLIED

Each sterile lens is supplied in a plastic blister package containing a phosphate buffered saline solution with 0.1% polyvinyl alcohol. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter and expiration date.