PACKAGE INSERT / FITTING GUIDE

BAUSCH+LOMB

# PureVision®2

(balafilcon A)

## Visibility Tinted Contact Lenses

℞ ONLY **CAUTION:** Federal law restricts this device to sale by or on the order of a licensed practitioner.



Printed in the USA

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## SYMBOL REFERENCE GUIDE

For label and cartons:

The following symbol is for the CE Quality Certification

CE 0050

Meets EU Packaging Directive

STERILE — Sterilized using steam

Caution

DIA $Ø_T$ — Diameter

EXP — Use-by date

LOT — Batch code

EC REP — Authorized representative in the European Community

℞ ONLY — Prescription only (USA)

PWR $F'_V$ — Power

BC — Base curve

Temperature limit

YYYY-MM-DD — Effective date

Manufacturer

8067604

## TABLE OF CONTENTS



## CAUTION

Federal law restricts this device to sale by or on the order of a licensed practitioner.

## IMPORTANT

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens and to illustrate fitting procedures. It is effective as of the date on the 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 practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.



## DESCRIPTION

The Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens is a soft hydrophilic contact lens which is available as a spherical lens. The lens material, balafilcon A, is a copolymer of a silicone vinyl carbamate, N-vinyl-pyrrolidone, a siloxane crosslinker and a vinyl alanine wetting monomer, and is 36% water by weight when immersed in a sterile borate buffered saline solution. This lens is tinted blue with up to 300 ppm of Reactive Blue Dye 246.

The physical / optical properties of the lens are:

| | |
|---|---|
| Specific Gravity: | 1.064 |
| Refractive Index: | 1.426 |
| Light Transmittance: | C.I.E. value—at least 95% |
| Water Content: | 36% |
| Oxygen Permeability: | $91 \times 10^{-11}$[$cm^3O_2$(STP) x cm]/(sec x $cm^2$ x mmHg) @ 35°C Polarographic Method (Boundary and Edge Corrected) |
| | $101 \times 10^{-11}$[$cm^3O_2$(STP) x cm]/(sec x $cm^2$ x mmHg) @ 35°C Polarographic Method (Boundary Corrected, Non-Edge Corrected) |

The Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lenses, with AerGel™ technology lens material, are manufactured by the FormCast™ manufacturing process, cast molding process, and are surface treated by the Performa™ surface treatment process which transforms hydrophobic silicone to hydrophilic silicate.

The Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens may be prescribed for Frequent/Planned Replacement or Disposable Wear.

## LENS PARAMETERS AVAILABLE

The Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

| | |
|---|---|
| Diameter: | 14.0mm |
| Center Thickness: | Varies with Power 0.070mm at -3.00D |
| Base Curve: | 8.6mm |
| Powers (Spherical): | +6.00D to -12.00D* |

*Additional powers may be introduced over time, check periodically for product availability.



## HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina. When placed on the cornea for therapeutic use, the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens acts as a bandage to protect the cornea and relieve pain during treatment of ocular pathologies.

## INDICATIONS

**Vision Correction**

The Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 30 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +8.00D to -20.00D when prescribed for up to 30 days of extended wear and from +20.00D to -20.00D for daily wear or extended wear up to 7 days.

**Therapeutic Use**

The Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens is also indicated for therapeutic use. Use as a bandage contact lens for corneal protection and corneal pain relief during treatment of ocular pathologies as well as post-surgical conditions. Applications of the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens include but are not limited to conditions such as the following:

- For corneal protection in conditions such as entropion, trichiasis, tarsal scars, recurrent corneal erosion and post surgical ptosis for corneal protection;
- For corneal pain relief in conditions such as bullous keratopathy, epithelial erosion and abrasion, filamentary keratitis, post-keratoplasty;
- For use as a bandage during the healing process of conditions such as chronic epithelial defects, corneal ulcer, neurotrophic keratitis, neuroparalytic keratitis, chemical burns, and post surgical epithelial defects.
- For post-surgical conditions that include bandage use such as LASIK, PRK, PK, PTK, lamellar grafts, corneal flaps, and additional corneal surgical conditions.

Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lenses for therapeutic use can also provide optical correction during healing if required.



**Frequent/Planned Replacement Wear**

When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb PureVision®2 (balafilcon A) 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 practitioner. The lens may be disinfected using a chemical disinfection system.

**Disposable Wear**

When prescribed for Disposable Wear, the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb PureVision®2 (balafilcon A) 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 PureVision®2 (balafilcon A) 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 practitioner'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 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.

**Extended Wear**

- The risk of microbial keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. 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 endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

  The long term risk of microbial keratitis has not been determined for this lens. A post-approval study with average follow-up of 15 months has been completed.

  The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners' views of extended wearing times 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 30 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses and promptly contact his or her eye care practitioner.**

## PRECAUTIONS

**Special Precautions for Eye Care Practitioners**

- Due to the small 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 practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The oxygen transmissibility is below the established threshold required to prevent overnight corneal edema for the extremes of the power range, above +3.00D and –5.00D.[1] In the US clinical study, the rate of infiltrative keratitis was found to be higher with higher lens powers (see Clinical Studies section of this package insert).
- 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 practitioner should carefully monitor the continuing ocular health of the patient and lens performance on eye.
- Eye care practitioners 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 practitioner.
- Some patients will not be able to tolerate continuous wear even if able to tolerate the same or another lens on a daily wear basis. Some patients who are able to tolerate continuous wear will not be able to wear their lenses continuously for 30 days. Patients should be carefully evaluated for continuous wear prior to prescription and dispensing, and eye care practitioners should conduct early and frequent follow-up examination to determine ocular response to continuous 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.

[1] *Holden BA, Mertz GW. Critical Oxygen Levels to Avoid Corneal Edema for Daily and Extended Wear Contact Lenses. Invest Ophthalmol Vis Sci 25:1162, 1984.*



- Aphakic patients should not be fitted with Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lenses until the determination is made that the eye has healed completely.

**In Addition, For Therapeutic Use**

- Close professional supervision is necessary for therapeutic use of Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lenses.
- Medications necessary for treatment should be used with caution under close supervision by the eye care practitioner.

Eye care practitioners should carefully instruct patients about the following lens care and safety precautions. For therapeutic use, in some circumstances only the eye care practitioner will insert and remove lenses and if so, patients should be instructed NOT to handle lenses themselves. It is strongly recommended that patients be provided with a copy of the Bausch + Lomb PureVision®2 (balafilcon A) 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-based cosmetics are less likely to damage lenses than oil-based products.
- Be sure that before leaving the eye care practitioner'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 PureVision®2 (balafilcon A) Visibility Tinted Contact Lens and those prescribed by the eye care practitioner.
- 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.
- For THERAPEUTIC USE, in some circumstances only the eye care practitioner will insert and remove lenses and if so, patients should be instructed NOT to handle lenses themselves.



**Solution Precautions**

**Do not use the Ultracare Disinfecting System or any of its components (Ultracare Disinfecting Solution, Ultracare Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrazyme Enzymatic Cleaner) to clean and disinfect the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens because the lens dimensions will be altered.**

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 practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to immediately consult his or her eye care practitioner.
- 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 at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

**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 practitioner 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 the lenses**.
- If the discomfort or problem stops, the patient should look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. The patient should place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, 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 his or her eye care practitioner.**

  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 practitioner** 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 staining 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.

During THERAPEUTIC USE, an adverse effect may be due to the original disease or injury or may be due to the effects of wearing a contact lens. There is a possibility that the existing disease or condition might become worse when a soft contact lens for therapeutic use is used to treat an already



diseased or damaged eye. The patient should be instructed to avoid serious eye damage by contacting the eye care practitioner IMMEDIATELY if there is any increase in symptoms while wearing the lens.

## CLINICAL STUDIES

The following clinical results are provided for informational purposes. It is important to note that the results below are from a study conducted with the Bausch + Lomb PureVision® Contact Lens which has the same lens material, but different lens design.

### PRE-APPROVAL EXTENDED WEAR STUDIES

### STUDY DESCRIPTION

**Study Design**

The objective of this 12-month study was to evaluate the safety and efficacy of the PureVision® (balafilcon A) Visibility Tinted Contact Lenses worn on a 30-day continuous wear basis, compared to a conventional control lens worn on a 7-day continuous wear basis. A total of 1640 eyes (820 subjects) were enrolled into this study. Subjects were fitted with a PureVision® Contact Lens on one eye while the contralateral eye was fitted with a control lens. Subjects were instructed to replace the PureVision® Contact Lens with a new lens every 30 days, and to wear the control lens overnight for up to six consecutive nights per week. Eyes had one night without lens wear after the scheduled removal. The control lens was to be replaced with a new lens every 14 days.

Six hundred ten (610) subjects completed the one-year study. Ten subjects discontinued in the daily wear adaptation period, 182 subjects discontinued during the extended wear phase and 18 subjects were not dispensed lenses.

**Patient Assessments**

Subjects were evaluated at follow-up visits scheduled after 24 hours, 10 days, 1 month, 3 months, 6 months, 9 months, and 12 months of lens wear.

**Demographics**

Subject recruitment was open to adapted and unadapted contact lens wearers. There were no restrictions as to the subject's gender or occupation, but subjects were required to be of legal age (typically 18 or 21) and have the legal capacity to volunteer. The ages of the subjects ranged from 18 to 74 years of age, with a mean age of 33.6, and included 574 females and 228 males, with a ratio of 2.52 females to every male. For the PureVision® Contact Lens the power range used was –0.50D to –9.00D. For the control lens the power range was –0.50D to –8.50D.

The previous lens wearing experience of the subjects that participated in the study was 5% no lens wear, 43% daily wear, and 51% continuous wear. The refractive errors of the subjects ranged from –0.25D to –11.75D, and included up to –2.00D of astigmatism.



### SUMMARY OF DATA ANALYSES

**Summary of Data Analyses**

The key endpoints for this study were:

1. Grade 2 and higher slit lamp findings (safety endpoint),
2. Grade 2 and higher corneal infiltrates (safety endpoint), and
3. Contact lens corrected visual acuity worse than 20/40 (efficacy endpoint).

For each key endpoint, the rates (incidents of endpoint/number of eyes) experienced by eyes in the PureVision® Contact Lenses and control lenses were calculated. The difference in rates between the two lens types was determined and a 95% confidence interval for the difference was calculated. For each key endpoint a "clinically significant difference" in the rates was established before the study started. These "clinically significant differences" were as follows: 10% for total slit lamp findings ≥ Grade 2, 5% for corneal infiltrates ≥ Grade 2, and 5% for the acuity endpoint. For example, if the true rates of endpoint infiltrates in the subject population were 9.9% in the PureVision® Contact Lens and 5% in the control lens, these rates would be considered substantially equivalent (difference <5%).

In order to be successful for a given endpoint, the upper 95% confidence limit for the difference in the study rates had to be less than the pre-established "clinically significant difference". This means that we are 95% confident that the true difference is within tolerance. The safety and efficacy goals were met for all three key endpoints. Results are as follows:

| | PureVision | | Control | | Relative Risk/ PureVision Control | Difference in % | Upper 95% Confidence Level | Clinically Significant Difference |
|---|---|---|---|---|---|---|---|---|
| Endpoint | n | % | n | % | | | | |
| Slit Lamp Findings ≥ Grade 2 | 138 | 17.5% | 139 | 17.6% | 1.0 | -0.1% | 2.6% | 10.0% |
| Corneal Infiltrates ≥ Grade 2 | 23 | 2.9% | 10 | 1.3% | 2.3 | 1.6% | 2.9% | 5.0% |
| Visual Acuity Worse than 20/40 | 0 | 0.0% | 2 | 0.3% | 0.0 | -0.3% | 0.1% | 5.0% |



**Summary of Slit Lamp Findings**

Slit lamp examinations were conducted at every study visit. Each graded slit lamp parameter was scored on a qualitative grade scale ranging from 0 to 4, with Grade 0 representing the absence of findings, and Grades 1 through 4 representing successively worse findings. For each study eye, a determination was made for each parameter as to whether, or not a positive finding was presented at any visit. The following table describes slit lamp findings ≥ Grade 2 and ungraded slit lamp findings.

| | PureVision | Control |
|---|---|---|
| Graded Slit Lamp Findings (≥ Grade 2) | | |
| **Any Finding**[1,2] | **17.5%** | **17.6%** |
| Corneal Staining | 8.2% | 8.4% |
| Limbal Injection | 3.7% | 4.3% |
| Bulbar Injection | 5.2% | 4.7% |
| Tarsal Conjunctival Abnormalities | 3.9% | 3.9% |
| **Corneal Infiltrates**[1] | **2.9%** | **1.3%** |
| Epithelial Edema | 1.3% | 1.4% |
| Epithelial Microcysts | 1.0% | 1.0% |
| Corneal Neovascularization | 1.0% | 1.7% |
| Ungraded Slit Lamp Findings | | |
| Other Anterior Segment Abnormalities[3] | 13.2% | 13.8% |
| External Adnexa Abnormalities | 2.7% | 2.7% |
| Conjunctivitis | 2.4% | 2.0% |
| Corneal Striae | 0.0% | 0.3% |

[1] Slit Lamp Finding and Corneal Infiltrates ≥ Grade 2 were the safety endpoints for this study.
[2] The total of all Graded slit lamp findings does not equal the category of Any Finding.
[3] The more common findings identified as Other Anterior Segment Abnormalities included: conjunctival staining; dimple veils; mucin balls; lipid deposits; and ghost vessels.

It should be noted that the Bausch + Lomb PureVision® Contact Lens and the control lens were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.

**Corneal Infiltrates**

The following table describes the rate of corneal infiltrates according to the lens power used.

| | Lens Power | Corneal Infiltrates (≥ Grade 2) |
|---|---|---|
| PureVision | Plano to – 3.00 | 1.7 % |
| | – 3.25 to – 6.00 | 3.2 % |
| | > – 6.00 | 6.4 % |
| | Total | 2.9 % |

| | Lens Power | Corneal Infiltrates (≥ Grade 2) |
|---|---|---|
| Control | Plano to – 3.00 | 0.9 % |
| | – 3.25 to – 6.00 | 1.5 % |
| | > – 6.00 | 1.3 % |
| | Total | 1.3 % |

**Other Lens-Related Adverse Events**

In addition to the outcomes described above, the following lens related adverse events were noted. This table does not include conjunctivitis or tarsal conjunctival abnormalities, e.g., giant papillary conjunctivitis.

**Other Important Lens-Related Adverse Events**

| | PureVision | Control |
|---|---|---|
| Corneal Scar | 14 (1.8 %) | 5 (0.6 %) |
| Other Ocular Inflammation* | 10 (1.3 %) | 2 (0.3 %) |
| Anterior Chamber Reaction | 2 (0.3 %) | 1 (0.1 %) |
| Permanent Loss of Vision | 0 (0.0 %) | 0 (0.0 %) |



* Other Ocular Inflammation includes episcleritis, scleritis, iritis/uveitis. This condition was reported in association with other conditions such as keratitis, corneal infiltrates, blepharitis, corneal abrasion, and contact lens over wear.

It should be noted that the PureVision® Contact Lens and control lenses were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.

**Efficacy Outcomes**

The contact lens visual acuity was measured at each scheduled and unscheduled follow-up visit throughout the one-year study. For the 610 subjects that completed the study, visual acuity of 20/20 or better was reported for 87% and 86% of the measurements for the PureVision® Contact Lens and control lens, respectively. Similarly, visual acuity of 20/25 or better was reported 98% and 97% of the times for the PureVision® Contact Lens and control lens.

**Wearing Time**

In this US clinical study subjects were required to maintain a minimum wearing time in order to continue in the study. For the subjects that completed the study, the average continuous wear time for the PureVision® Contact Lens was at least 28.0 days per month, from the 2-month visit through the 12-month visit. At these visits the same subjects reported they were able to wear the PureVision® Contact Lens at least 22 days continuously 94% of the times they were asked.

During the course of the study, 15 subjects were discontinued from the study because they were not able to wear the PureVision® Contact Lens for 30 days. Twenty-one (21) subjects were discontinued from the study because they were not able to wear the control lens for 7 days.

**Overnight Corneal Swelling**

Two separate studies assessed the corneal swelling response induced by overnight contact lens wear. In the first study, 30 subjects each wore either a +3.00D, –3.00D, or –9.00D PureVision® Contact Lens and an equivalent power lens made from a conventional hydrogel material (control lens) on the contralateral eye overnight under closed eye conditions for approximately eight hours. The corneal swelling, measured as the percent increase in the center thickness of the cornea, with the control lens (9.1%) was significantly greater than that measured in conjunction with the PureVision® Contact Lenses (4.1%). In the second study, the corneal swelling response was measured under similar conditions. In this study the response to a –3.00D PureVision® Contact Lens (3.0%) was compared to the swelling response to no lens wear (1.9%). The responses were not statistically different (p-value > 0.05).

**POST-APPROVAL EXTENDED WEAR STUDY**

The purpose of this post-approval study was to investigate the occurrence of serious adverse events with the PureVision® Contact Lens when worn on a 30-day continuous wear basis. Serious adverse events were any case of microbial keratitis (infected corneal ulcer) or a loss of more than two lines of best corrected visual acuity.



**Study Design**

The intent of the study was to enroll up to 6,500 subjects who would account for 4,500 to 5,000 subject-years of lens wear enrolled by a minimum of 100 Investigators. Study lenses were dispensed to 6,412 subjects who provided 5,054 patient-years of compliant wear while being followed by 158 Investigators. The age of the eligible subjects dispensed study lenses ranged from 12 to 85, with a mean age of 36 years and a ratio of 1.74 female subjects for every male. The spherical refractive error of subjects ranged from +10.00D to -15.00D with a mean of -3.4D.

A subject was eligible for entry into the study if the subject:

1. was, in the opinion of the Investigator, suitable for continuous soft contact lens wear;
2. agreed to wear lenses on a 30-day continuous wear basis; and
3. was age 12 or older.

The study protocol did not define exclusion criteria. Subjects that in the opinion of the Investigator were not suitable for continuous wear were excluded from the study. The Investigators were not required to describe preexisting conditions that precluded enrollment.

The study was divided into two phases: Phase 1 lasted for approximately 12 months; Phase 2 was considered optional and consisted of the duration of time a subject was in PureVision® Contact Lenses following completion of Phase 1. The maximum length of Phase 2 was 3 years.

In both phases, each subject wore a PureVision® Contact Lens on each eye on a 30-day continuous wear basis. Lenses were worn overnight without removal for 22-29 consecutive nights, and were removed and replaced with new lenses on the morning of the 30th day.

Follow-up visits were scheduled at 6-month intervals following the Enrollment Visit. At the Enrollment Visit and at all scheduled and unscheduled Follow-Up visits, the Investigator evaluated the best corrected spherocylindrical refractive visual acuity and examined the subject for corneal scarring and/or indications of microbial keratitis. The subjects were also questioned regarding their compliance with the lens wear schedule.

The last scheduled follow-up visit during Phase 2 was the 48-Month Visit. If a subject exited the study in Phase 2 before the 48-Month Visit, the subject was considered completed, if he/she completed a 12-Month Visit or later. The duration of the study extended until the time that the last subject enrolled had completed 12 months of contact lens wear in Phase 1.

All reports of possible microbial keratitis, any report by a clinical investigator of the presence of a new corneal scar or other indication of microbial keratitis, were subjected to a multi-stage evaluation process. A thorough case review for all reports of new corneal scars or other indications of microbial keratitis was completed by a Bausch + Lomb clinician who eliminated cases with clear evidence refuting a microbial



keratitis diagnosis. Then a panel of three Bausch + Lomb clinicians reviewed each of the remaining cases, and compared the clinical findings to the study definition of microbial keratitis. The records of the suspect microbial keratitis cases, the opinions and diagnosis of the independent Clinical Investigator and information from any other treating physician were reviewed by the panel and Bausch + Lomb Chief Medical Officer for a final determination.

**Results**

Of the 6,412 subjects dispensed study lenses, there were 7 cases of microbial keratitis reported for 7 individual subjects. No subject was diagnosed with microbial keratitis in both eyes. The table below presents a summary of the occurrence rates for microbial keratitis, new corneal scars or other indication of microbial keratitis, or permanent decrease in visual acuity of 2 or more lines.

| | Cases | Patient-Years | Annual Incidence* | 95%CI* |
|---|---|---|---|---|
| **Microbial Keratitis** | | | | |
| **All Years** | 7 | 5054 | 13.9 | (3, 25) |
| **First Year** | 7 | 3779.5 | 18.5 | (3, 34) |
| **New Corneal Scar or Other Reports Suggestive of Microbial Keratitis** | | | | |
| **All Years** | 35 | 5154.5 | 67.9 | (45, 91) |
| **First Year** | 34 | 3843 | 88.5 | (58, 119) |
| **Permanent Decrease in Visual Acuity of 2 or More Lines** | | | | |
| All Years | 0 | 5054 | 0 | (0, 0.98) |
| First Year | 0 | 3779.5 | 0 | (0, 1.3) |

*/ Per 10,000 patient-years*

Patient-years were calculated considering various periods of compliant lens wear. The subjects that wore their lenses, on average, for 3 weeks out of each 4-week period, for all periods of wear contributed 5,054 patient-years of wear. With 7 cases of microbial keratitis for 5,054 patient-years, the incidence of microbial keratitis is 13.9 cases per 10,000 patient-years of lens wear.

The total wear time for compliant subjects over the first year of participation in the study contributed 3779.5 patient-years of wear. This results in an incidence of microbial keratitis of 18.5 cases per 10,000 patient-years of lens wear.



There were no confirmed cases of a permanent best corrected visual acuity decrease of more than two lines related to lens wear including the 7 subjects that presented with microbial keratitis. Fifteen subjects were reported to have a best corrected visual acuity decrease of more than two lines during all periods of compliant lens wear that were classified as not lens related. Reasons for these decreases in vision included a retinal hemorrhage, retinal detachments and cataracts.

**Conclusions**

The incidence of microbial keratitis associated with 30 days of continuous wear of PureVision® Contact Lenses was 13.9 cases per 10,000 patient-years of lens wear. The 95% confidence interval around this estimate is 3 to 25 cases per 10,000 patient-years of lens wear. None of the subjects presenting with microbial keratitis experienced a permanent decrease of visual acuity of more than two lines.

**Study Strengths**

This was a prospective study that followed a large number of subjects, 6,412, with a wide range of ages over an extended period of time, up to 3.5 years, by a large number of varied Investigators, 158. The study was a surveillance of the performance of the lens in a wide variety of practice settings rather than a controlled clinical trial. The study endpoints were predetermined, easily understood, and well defined including a detailed definition of microbial keratitis. Incidence rates were based on subjects compliant with the full 30-day wearing period. Cases were classified by experienced clinical researchers.

**Study Limitations**

Prospective surveillance studies are useful in providing estimates of specific risks that occur infrequently; however, there can be limitations. The study was not a controlled trial with rigorous follow-up. The selection of Investigators was open to all practitioners, some of who may not have fully appreciated the commitment of participating in a surveillance study. With this wide variety of Investigators, there was variability in documentation, treatment and subjective language in medical records. Compliance with lens wear requirements was based on periodic reports by subjects. The classification of microbial keratitis was determined by clinical researchers who had direct communication with the Investigator, but did not have direct contact with the subject or photographs.

The Study Strengths and Study Limitations should be considered when evaluating the significance of the results.

**THERAPEUTIC USE STUDIES**

**Introduction**

Two prospective open-ended non-randomized clinical trials were conducted to evaluate PureVision® Contact Lenses as continuous wear lenses for therapeutic applications. The studies, conducted in Asia, included subjects who presented at the two centers requiring continuous lens wear for relief of corneal pain, a bandage during the healing process of certain corneal conditions and corneal protection.



**STUDY # 1**

**Study Description**

A total of 54 eyes of 54 patients were reported with a mean wearing time of 11 months (range from 1 day to 11 months). Twenty-eight (52%) of the subjects were male and 26 (48%) were female with an average age 50 years (range from 4 to 79 years old).

Thirty-six of the fifty-four subjects (67%) were post-surgical cases including post-surgical treatment after refractive laser assisted in-situ keratomileusis (LASIK), photorefractive keratectomy (PRK), phototherapeutic keratoplasty (PTK), and penetrating keratoplasty (PK), corneal grafts, conjunctival flaps, vitrectomy, tumor excision of the conjunctiva, anterior stromal puncture, and phacoemulsification leak repair. A total of 7 cases for bullous keratopathy, 3 cases of chemical burn, 3 cases of epithelial abrasion or recurrent erosion, 3 cases of corneal perforation, 1 case neurotrophic ulcer, and 1 case corneal laceration were also treated.

**Data Analysis and Results:**

Where corneal pain relief was one of the treatment goals, twenty-seven of the 28 (96%) cases were considered successful with complete or considerable pain relief and an additional patient reported partial pain relief (4%). Of the forty cases where the lens was used as a bandage during corneal healing was one of the goals, total success was achieved in 83% (33/40) of the cases and partial success was achieved in 96% (38/40) of the cases. All twenty one cases (100%) of the subjects needing corneal protection were effective.

**STUDY # 2**

**Study Description**

A total of 30 eyes of 28 subjects were fitted with the PureVision® Contact Lens with a mean wear time of 25.2 days (ranging from 3 days to 3 months). Nineteen (68%) of the subjects were male and 9 (32%) were female with an age range from 9 years to 55 years.

Lens wearing categories included post-surgical bandage use in 27 cases (post-PK, post-deep lamellar keratoplasty, pterygium excision, conjunctival allograft, peripheral ulcerative keratitis, descemetocele, post-chemical burns, and corneal perforation from severe dry eye), mechanical support use for 1 case of bullous keratopathy, symptomatic corneal pain relief for 1 case of filamentary keratitis and healing adjunct in 1 case of a non-healing corneal abrasion.

**Data Analysis and Results:**

Therapeutic success was reported in 83% of the eyes where the lens was used as a post-surgical bandage, and 100% in each case of mechanical support (3), epithelial abnormalities (1), bullous keratopathy (1), and filamentary keratitis (1). Fifteen of 19 eyes (79%) with post-surgical epithelial defects were successful within 3 days to 3 weeks. All subjects reported symptomatic relief. Complications included infectious keratitis in 2 subjects that were being treated for post-PK persistent epithelial defect and corneal vascularization observed in one case where the cornea was already compromised due to a grade 4 alkali injury. The investigators reported the overall study therapeutic success in 87% (26/30) of the eyes.



## SELECTION OF PATIENTS

The eye care practitioner should not fit patients who cannot or will not adhere to a recommended care or replacement regimen, 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 PureVision®2 (balafilcon A) Visibility Tinted Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner 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 practitioner.

## 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 post-fitting examination results can be compared.

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

**2. Initial Lens Power Selection**

- Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. Select the appropriate lens and place on the eye.



- 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.
- 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, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

**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.

- 24 hours
- 10 days
- 1 month
- 3 months
- Every six months thereafter

At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief. Depending on the patient's prior experience with contact lenses and/or continuous wear, the eye care practitioner may consider prescribing a one week period of daily wear adaptation prior to beginning continuous wear.

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. If the patient is wearing the lenses for continuous wear, the follow-up examination should be conducted as early as possible the morning after overnight 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.



## PRACTITIONER FITTING SETS

Lenses must be discarded after a single use and must not be used from patient to patient.

## WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, 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 practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

**Continuous Wear (Greater than 24 hours or While Asleep):**

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Bausch + Lomb recommends beginning continuous wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of continuous wear one night at a time, unless individual considerations indicate otherwise. The professional should examine the patient in the early stages of continuous 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 practitioner. (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 practitioner.**

**Disposable Lens Wear**

No lens care is needed. The lenses are discarded every time they are removed from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available.

**Frequent/Planned Replacement**

When removed between replacement periods, lenses must be cleaned and disinfected before reinsertion, or be discarded and replaced with a new lens.

**Therapeutic Lens Wear**

Close professional supervision is necessary and strongly recommended. Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lenses can be worn on a continuous wear basis for up to 30 nights and days or for shorter periods as directed by the eye care practitioner. The eye care practitioner should provide specific instructions regarding lens care, removal, and insertion. In some cases, only the eye care practitioner should handle the lens insertion and removal.



## 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 PureVision®2 (balafilcon A) Visibility Tinted Contact Lenses.

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 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 diopter 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 fingernails. 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 are 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 practitioner in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.**

## LENS CARE

**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 practitioner 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 practitioner, the specific instructions for such products and the particular characteristics of the patient. For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch + Lomb PureVision®2 (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.

**a. Soaking and Storing Lenses**
***Instruction for Use:***
Use only fresh contact lens disinfecting solution each time you soak (store) lenses.

**WARNING:**
Do not reuse or "top-off" old solution left in lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in the case.

**b. Rub and Rinse Time**
***Instruction for Use:***
Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.

**WARNING:**

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



**c. Lens Case Care**
***Instruction for Use:***

- Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. **Never use water.** Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions **(never use water)** and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air drying, be sure that no residual solution remains in the case before allowing it to air-dry.
- Replace lens case according to the directions given by your eye care practitioner or the labeling that came with your case.
- Contact lens cases can be a source of bacterial growth.

**WARNING:**
Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

**d. Water Activity**
***Instruction for Use:***
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 your lenses have been submersed in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing lenses during any activity involving water.

**e. Discard Date on Solution Bottle**
***Instruction for Use:***
Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking contact lenses.

**WARNING:**
Using solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

## CARE FOR A STICKING (NON-MOVING) 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 practitioner 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 practitioner.



## EMERGENCIES

The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb PureVision®2 (balafilcon A) 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 US, Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000 (Option 1 - English, Option 2 - French)

## HOW SUPPLIED

Each sterile lens is supplied in a plastic blister package containing borate buffered saline solution which may contain poloxamine 1107. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter and expiration date. Store lenses at room temperature 15° to 25°C (59° to 77°F).

PACKAGE INSERT / FITTING GUIDE

BAUSCH+LOMB

# PureVision®2 (balafilcon A)

## Visibility Tinted Contact Lenses

## For Astigmatism

℞ ONLY **CAUTION:** Federal law restricts this device to sale by or on the order of a licensed practitioner.



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

Printed in the USA

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8129204

## SYMBOL REFERENCE GUIDE

For labels and cartons:

The following symbol is for the CE Quality Certification
CE 0050

Meets EU Packaging Directive

STERILE Sterilized using steam

Caution

DIA $Ø_T$ Diameter

EXP Use-by date

LOT Batch code

EC REP Authorized representative in the European Community

℞ ONLY Prescription only (USA)

PWR $F'_V$ Power

BC Base curve

SPH Sphere power

AX Cylinder axis

CYL Cylinder power

Temperature limit

YYYY-MM-DD Effective date

Manufacturer

8 1 2 9 2 0 4

## TABLE OF CONTENTS



## IMPORTANT

This package insert and fitting guide has been developed to provide practitioners with information covering characteristics of the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens and to illustrate fitting procedures. It is effective as of the date on the 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 practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.

## DESCRIPTION

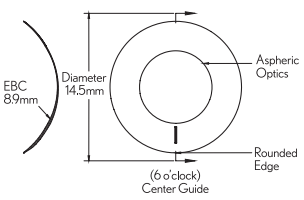
The Bausch + Lomb PureVision® 2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens is a soft hydrophilic contact lens that is available as a flexible shell with a toric surface. The lens material, balafilcon A, is a copolymer of a silicone vinyl carbamate, N-vinyl-pyrrolidone, a siloxane crosslinker, and a vinyl alanine wetting monomer, and is 36% water by weight when immersed in a sterile borate buffered saline solution. This lens is tinted blue with up to 300 ppm of Reactive Blue Dye 246.

The physical / optical properties of the lens are:

| | |
|---|---|
| Specific Gravity: | 1.064 |
| Refractive Index: | 1.426 |
| Light Transmittance: | C.I.E. value—at least 95% |
| Water Content: | 36% |
| Oxygen Permeability: | $91 \times 10^{-11}$[$cm^3O_2$(STP) x cm]/(sec x $cm^2$ x mmHg) @ 35°C Polarographic Method (Boundary and Edge Corrected) |
| | $101 \times 10^{-11}$[$cm^3O_2$(STP) x cm]/(sec x $cm^2$ x mmHg) @ 35°C Polarographic Method (Boundary Corrected, Non-Edge Corrected) |

The Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens, with AerGel™ technology lens material, is manufactured by a cast molding process and is treated by the Performa™ surface treatment process, which transforms hydrophobic silicone to hydrophilic silicate. The Auto Align Design™ is a ballasting geometry designed for lens orientation stability.






*Aspheric optical surfaces designed to reduce the population average spherical aberration across all sphere, cylinder, and axis combinations.*

*A hybrid ballasting geometry designed to optimize thickness from apex to base of lens and offer excellent orientation and alignment.*

*A smooth rounded profile designed to provide comfort plus optimal movement over the conjunctival tissue.*

**Guide Mark System**

Each Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens is marked with 1 Guide Mark in the lens perimeter at 6 o'clock. This Guide Mark gives an instant reference for estimating lens rotation and orientation. It is in effect a protractor guide on the lens surface. The guide mark makes proper axis orientation and fitting faster and easier.

## LENS PARAMETERS AVAILABLE

The Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

| | |
|---|---|
| Diameter: | 14.5mm |
| Center Thickness: | Varies with Power<br>0.099mm at -3.00D |
| Base Curve: | 8.9mm |
| Sphere Powers: | +6.00D to -9.00D in 0.25D steps<br>(0.50D steps above –6.00D)* |
| Cylinder Powers: | –0.75D, –1.25D, –1.75D, and -2.25D |
| Axis: | 10° to 180° in 10° increments |

**Additional powers may be introduced over time; check for product availability.*

## HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens has a unique hybrid ballasting design that results in excellent stability and when placed on the cornea acts as a refracting medium to focus light rays on the retina.



## INDICATIONS

**Vision Correction**

The Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 30 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, which does not interfere with visual acuity. The lens may be prescribed for Frequent / Planned Replacement Wear or Disposable Wear in spherical powers ranging from +6.00D to -9.00D when prescribed for up to 30 days of extended wear and from +20.00D to –20.00D for daily wear or extended wear up to 7 days.

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

**FREQUENT / PLANNED REPLACEMENT WEAR**

When prescribed for Frequent / Planned Replacement Wear, the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) 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 practitioner. The lens may be disinfected using a chemical disinfection system.

**DISPOSABLE WEAR**

When prescribed for Disposable Wear, the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) 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 that is to be used to care for the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) 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 practitioner'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 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.

**EXTENDED WEAR**

- The risk of microbial 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 that 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 endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.
- The long-term risk of microbial keratitis has not been determined for this lens. A post-approval study with average follow-up of 15 months has been completed.
- The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, professionals' views of extended wearing times 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 30 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care practitioner.

## PRECAUTIONS

**Precautions for Eye Care Practitioners**

- 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 practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The oxygen transmissibility is below the established threshold required to prevent overnight corneal edema for portions of the power range, including plus powers and some low minus power lenses.[1] In the US clinical study of the Bausch + Lomb PureVision® (spherical) lens, the rate of infiltrative keratitis was found to be higher with higher lens powers (see Clinical Studies section of the package insert).
- 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 practitioner should carefully monitor the continuing ocular health of the patient and lens performance on eye.

*[1]Holden BA, Mertz GW. Critical Oxygen Levels to Avoid Corneal Edema for Daily and Extended Wear Contact Lenses. Invest Ophthalmol Vis Sci 25:1162, 1984.*



- Eye care practitioners 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 practitioner.
- Some patients will not be able to tolerate continuous wear even if able to tolerate the same or another lens on a daily wear basis. Some patients who are able to tolerate continuous wear will not be able to wear their lenses continuously for 30 days. Patients should be carefully evaluated for continuous wear prior to prescription and dispensing, and eye care practitioners should conduct early and frequent follow-up examination to determine ocular response to continuous wear.
- As with any contact lens, follow-up visits are necessary to ensure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.
- Aphakic patients should not be fitted with Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lenses until the determination is made that the eye has healed completely.

Eye care practitioners 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 PureVision®2 For Astigmatism (balafilcon A) 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-based cosmetics are less likely to damage lenses than oil-based products.
- Be sure that before leaving the eye care practitioner'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 PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens and those prescribed by the eye care practitioner.
- 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**

**Do not use the Ultracare Disinfecting System or any of its components (Ultracare Disinfecting Solution, Ultracare Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrazyme Enzymatic Cleaner) to clean and disinfect the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens because the lens dimensions will be altered.**

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 practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- 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 practitioner.

**Topics to Discuss with the Patient**

- As with any contact lens, follow-up visits are necessary to ensure 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 practitioner 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 the lenses**.
- If the discomfort or problem stops, the patient should look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. The patient should place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, 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 his or her eye care practitioner.**
- 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 practitioner** 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 staining 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.



## CLINICAL STUDIES

The following clinical results are provided for informational purposes. It is important to note that the results below are from studies conducted with the Bausch + Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lens, which has the same lens material but different lens design (spherical). The studies were conducted with subjects not requiring astigmatic correction.

**PRE-APPROVAL EXTENDED WEAR STUDIES**

**STUDY DESCRIPTION**

**Study Design**

The objective of this 12-month study was to evaluate the safety and efficacy of the Bausch + Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lenses worn on a 30-day continuous wear basis, compared to a conventional control lens worn on a 7-day continuous wear basis. A total of 1640 eyes (820 subjects) were enrolled into this study. Subjects were fitted with a Bausch + Lomb PureVision® Contact Lens on one eye while the contralateral eye was fitted with a control lens. Subjects were instructed to replace the Bausch + Lomb PureVision® Contact Lens with a new lens every 30 days and to wear the control lens overnight for up to six consecutive nights per week. Eyes had one night without lens wear after the scheduled removal. The control lens was to be replaced with a new lens every 14 days.

Six hundred ten (610) subjects completed the one-year study. Ten subjects discontinued in the daily wear adaptation period, 182 subjects discontinued during the extended wear phase and 18 subjects were not dispensed lenses.

**Patient Assessments**

Subjects were evaluated at follow-up visits scheduled after 24 hours, 10 days, 1 month, 3 months, 6 months, 9 months, and 12 months of lens wear.

**Demographics**

Subject recruitment was open to adapted and unadapted contact lens wearers. There were no restrictions as to the subject's gender or occupation, but subjects were required to be of legal age (typically 18 or 21) and have the legal capacity to volunteer. The ages of the subjects ranged from 18 to 74 years of age, with a mean age of 33.6, and included 574 females and 228 males, with a ratio of 2.52 females to every male. For the Bausch + Lomb PureVision® Contact Lens, the power range used was –0.50D to –9.00D. For the control lens, the power range was –0.50D to –8.50D.

The previous lens wearing experience of the subjects that participated in the study was 5% no lens wear, 43% daily wear, and 51% continuous wear. The refractive errors of the subjects ranged from –0.25D to –11.75D, and included up to –2.00D of astigmatism.



**SUMMARY OF DATA ANALYSES**

**Summary of Data Analyses**

The key endpoints for this study were:

1. Grade 2 and higher slit lamp findings (safety endpoint),
2. Grade 2 and higher corneal infiltrates (safety endpoint), and
3. Contact lens corrected visual acuity worse than 20/40 (efficacy endpoint).

For each key endpoint, the rates (incidents of endpoint/number of eyes) experienced by eyes in the Bausch + Lomb PureVision® Contact Lens and control lenses were calculated. The difference in rates between the two lens types was determined and a 95% confidence interval for the difference was calculated. For each key endpoint a "clinically significant difference" in the rates was established before the study started. These "clinically significant differences" were as follows: 10% for total slit lamp findings ≥ Grade 2, 5% for corneal infiltrates ≥ Grade 2, and 5% for the acuity endpoint. For example, if the true rates of endpoint infiltrates in the subject population were 9.99% in the Bausch + Lomb PureVision® Contact Lens and 5% in the control lens, these rates would be considered substantially equivalent (difference <5%).

In order to be successful for a given endpoint, the upper 95% confidence limit for the difference in the study rates had to be less than the pre-established "clinically significant difference." This means that we are 95% confident that the true difference is within tolerance. The safety and efficacy goals were met for all three key endpoints. Results are as follows:

| | PureVision® | | Control | | Relative Risk/ PureVision® Control | Difference in % | Upper 95% Confidence Level | Clinically Significant Difference |
|---|---|---|---|---|---|---|---|---|
| Endpoint | n | % | n | % | | | | |
| Slit Lamp Findings ≥ Grade 2 | 138 | 17.5% | 139 | 17.6% | 1.0 | -0.1% | 2.6% | 10.0% |
| Corneal Infiltrates ≥ Grade 2 | 23 | 2.9% | 10 | 1.3% | 2.3 | 1.6% | 2.9% | 5.0% |
| Visual Acuity Worse than 20/40 | 0 | 0.0% | 2 | 0.3% | 0.0 | -0.3% | 0.1% | 5.0% |



**Summary of Slit Lamp Findings**

Slit lamp examinations were conducted at every study visit. Each graded slit lamp parameter was scored on a qualitative grade scale ranging from 0 to 4, with Grade 0 representing the absence of findings, and Grades 1 through 4 representing successively worse findings. For each study eye, a determination was made for each parameter as to whether or not a positive finding was presented at any visit. The following table describes slit lamp findings ≥ Grade 2 and ungraded slit lamp findings.

| | PureVision® | Control |
|---|---|---|
| Graded Slit Lamp Findings ( ≥ Grade 2 ) | | |
| **Any Finding[1,2]** | **17.5%** | **17.6%** |
| Corneal Staining | 8.2% | 8.4% |
| Limbal Injection | 3.7% | 4.3% |
| Bulbar Injection | 5.2% | 4.7% |
| Tarsal Conjunctival Abnormalities | 3.9% | 3.9% |
| **Corneal Infiltrates[1]** | **2.9%** | **1.3%** |
| Epithelial Edema | 1.3% | 1.4% |
| Epithelial Microcysts | 1.0% | 1.0% |
| Corneal Neovascularization | 1.0% | 1.7% |
| Ungraded Slit Lamp Findings | | |
| Other Anterior Segment Abnormalities[3] | 13.2% | 13.8% |
| External Adnexa Abnormalities | 2.7% | 2.7% |
| Conjunctivitis | 2.4% | 2.0% |
| Corneal Striae | 0.0% | 0.3% |

[1] Slit Lamp Finding and Corneal Infiltrates ≥ Grade 2 were the safety endpoints for this study.
[2] The total of all Graded slit lamp findings does not equal the category of Any Finding.
[3] The more common findings identified as Other Anterior Segment Abnormalities included: conjunctival staining, dimple veils, mucin balls, lipid deposits, and ghost vessels.

It should be noted that the Bausch + Lomb PureVision® Contact Lens and the control lens were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.



**Corneal Infiltrates**

The following table describes the rate of corneal infiltrates according to the lens power used.

| | Lens Power | Corneal Infiltrates (≥ Grade 2) |
|---|---|---|
| PureVision® | Plano to – 3.00 | 1.7 % |
| | – 3.25 to – 6.00 | 3.2 % |
| | > – 6.00 | 6.4 % |
| | Total | 2.9 % |

| | Lens Power | Corneal Infiltrates (≥ Grade 2) |
|---|---|---|
| Control | Plano to – 3.00 | 0.9 % |
| | – 3.25 to – 6.00 | 1.5 % |
| | > – 6.00 | 1.3 % |
| | Total | 1.3 % |

**Other Lens-Related Adverse Events**

In addition to the outcomes described above, the following lens-related adverse events were noted. This table does not include conjunctivitis or tarsal conjunctival abnormalities, e.g., giant papillary conjunctivitis.

**Other Important Lens-Related Adverse Events**

| | PureVision® | Control |
|---|---|---|
| Corneal Scar | 14 (1.8 %) | 5 (0.6 %) |
| Other Ocular Inflammation* | 10 (1.3 %) | 2 (0.3 %) |
| Anterior Chamber Reaction | 2 (0.3 %) | 1 (0.1 %) |
| Permanent Loss of Vision | 0 (0.0 %) | 0 (0.0 %) |

* Other Ocular Inflammation includes episcleritis, scleritis, and iritis/uveitis. This condition was reported in association with other conditions such as keratitis, corneal infiltrates, blepharitis, corneal abrasion, and contact lens over wear.

It should be noted that the Bausch + Lomb PureVision® Contact Lens and control lenses were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.

**Efficacy Outcomes**

The contact lens visual acuity was measured at each scheduled and unscheduled follow-up visit throughout the one-year study. For the 610 subjects that completed the study, visual acuity of 20/20 or better was reported for 87% and 86% of the measurements for the Bausch + Lomb PureVision® Contact Lens and control lens, respectively. Similarly, visual acuity of 20/25 or better was reported 98% and 97% of the times for the Bausch + Lomb PureVision® Contact Lens and control lens.

**Wearing Time**

In this US clinical study, subjects were required to maintain a minimum wearing time in order to continue in the study. For the subjects that completed the study, the average continuous wear time for the Bausch + Lomb PureVision® Contact Lens was at least 28.0 days per month, from the 2-Month visit through the 12-Month visit. At these visits, the same subjects reported they were able to wear the Bausch + Lomb PureVision® Contact Lens at least 22 days continuously 94% of the times they were asked.

During the course of the study, 15 subjects were discontinued from the study because they were not able to wear the Bausch + Lomb PureVision® Contact Lens for 30 days. Twenty-one (21) subjects were discontinued from the study because they were not able to wear the control lens for 7 days.

**Overnight Corneal Swelling**

A study was conducted to assess the corneal swelling response induced by overnight contact lens wear. Twenty-four (24) subjects each wore either a -3.00 -0.75 x 180° Bausch + Lomb PureVision® Toric Contact Lens (Test Lens) or a -3.00D Bausch + Lomb PureVision® Contact Lens (control lens) on the contralateral eye overnight under closed eye conditions for approximately eight hours. The corneal swelling, measured as the percent increase in the center thickness of the cornea, of the eyes wearing a Bausch + Lomb PureVision® Toric Lens (4.1%) was compared to the swelling response to the control lens (3.6 %). The responses were not statistically different (p-value > 0.20).

**POST-APPROVAL EXTENDED WEAR STUDY**

The purpose of this post-approval study was to investigate the occurrence of serious adverse events with the Bausch + Lomb PureVision® Contact Lens when worn on a 30-day continuous wear basis. Serious adverse events were any case of microbial keratitis (infected corneal ulcer) or a loss of more than two lines of best corrected visual acuity.



**Study Design**

The intent of the study was to enroll up to 6,500 subjects who would account for 4,500 to 5,000 subject-years of lens wear enrolled by a minimum of 100 Investigators. Study lenses were dispensed to 6,412 subjects who provided 5,054 patient-years of compliant wear while being followed by 158 Investigators. The age of the eligible subjects dispensed study lenses ranged from 12 to 85, with a mean age of 36 years and a ratio of 1.74 female subjects for every male. The spherical refractive error of subjects ranged from +10.00D to -15.00D with a mean of -3.4D.

A subject was eligible for entry into the study if the subject:

1. was, in the opinion of the Investigator, suitable for continuous soft contact lens wear;
2. agreed to wear lenses on a 30-day continuous wear basis; and
3. was age 12 or older.

The study protocol did not define exclusion criteria. Subjects that in the opinion of the Investigator were not suitable for continuous wear were excluded from the study. The Investigators were not required to describe preexisting conditions that precluded enrollment.

The study was divided into two phases: Phase 1 lasted for approximately 12 months; Phase 2 was considered optional and consisted of the duration of time a subject was in Bausch + Lomb PureVision® lenses following completion of Phase 1. The maximum length of Phase 2 was 3 years.

In both phases, each subject wore a Bausch + Lomb PureVision® Contact Lens on each eye on a 30-day continuous wear basis. Lenses were worn overnight without removal for 22-29 consecutive nights and were removed and replaced with new lenses on the morning of the 30th day.

Follow-up visits were scheduled at 6-month intervals following the Enrollment Visit. At the Enrollment Visit and at all scheduled and unscheduled Follow-Up visits, the Investigator evaluated the best corrected spherocylindrical refractive visual acuity and examined the subject for corneal scarring and/or indications of microbial keratitis. The subjects were also questioned regarding their compliance with the lens wear schedule.

The last scheduled follow-up visit during Phase 2 was the 48-Month Visit. If a subject exited the study in Phase 2 before the 48-Month Visit, the subject was considered completed, if he/she completed a 12-Month Visit or later. The duration of the study extended until the time that the last subject enrolled had completed 12 months of contact lens wear in Phase 1.



All reports of possible microbial keratitis, any report by a clinical investigator of the presence of a new corneal scar or other indication of microbial keratitis, were subjected to a multi-stage evaluation process. A thorough case review for all reports of new corneal scars or other indications of microbial keratitis was completed by a Bausch + Lomb clinician who eliminated cases with clear evidence refuting a microbial keratitis diagnosis. Then a panel of three Bausch + Lomb clinicians reviewed each of the remaining cases, and compared the clinical findings to the study definition of microbial keratitis. The records of the suspect microbial keratitis cases, the opinions and diagnosis of the independent Clinical Investigator and information from any other treating physician were reviewed by the panel and Bausch + Lomb Chief Medical Officer for a final determination.

**Results**

Of the 6,412 subjects dispensed study lenses, there were 7 cases of microbial keratitis reported for 7 individual subjects. No subject was diagnosed with microbial keratitis in both eyes. The table below presents a summary of the occurrence rates for microbial keratitis, new corneal scars or other indication of microbial keratitis, or permanent decrease in visual acuity of 2 or more lines.

| | Cases | Patient-Years | Annual Incidence* | 95%CI* |
|---|---|---|---|---|
| **Microbial Keratitis** | | | | |
| All Years | 7 | 5054 | 13.9 | (3, 25) |
| First Year | 7 | 3779.5 | 18.5 | (3, 34) |
| **New Corneal Scar or Other Reports Suggestive of Microbial Keratitis** | | | | |
| All Years | 35 | 5154.5 | 67.9 | (45, 91) |
| First Year | 34 | 3843 | 88.5 | (58, 119) |
| **Permanent Decrease in Visual Acuity of 2 or More Lines** | | | | |
| All Years | 0 | 5054 | 0 | (0, 0.98) |
| First Year | 0 | 3779.5 | 0 | (0, 1.3) |

**/ Per 10,000 patient-years*

Patient-years were calculated considering various periods of compliant lens wear. The subjects that wore their lenses, on average, for 3 weeks out of each 4-week period for all periods of wear contributed 5,054 patient-years of wear. With 7 cases of microbial keratitis for 5,054 patient-years, the incidence of microbial keratitis is 13.9 cases per 10,000 patient-years of lens wear.



The total wear time for compliant subjects over the first year of participation in the study contributed 3779.5 patient-years of wear. This results in an incidence of microbial keratitis of 18.5 cases per 10,000 patient-years of lens wear.

There were no confirmed cases of a permanent best corrected visual acuity decrease of more than two lines related to lens wear, including the 7 subjects that presented with microbial keratitis. Fifteen subjects were reported to have a best corrected visual acuity decrease of more than two lines during all periods of compliant lens wear that were classified as not lens-related. Reasons for these decreases in vision included a retinal hemorrhage, retinal detachments and cataracts.

**Conclusions**

The incidence of microbial keratitis associated with 30 days of continuous wear of Bausch + Lomb PureVision® Contact Lenses was 13.9 cases per 10,000 patient-years of lens wear. The 95% confidence interval around this estimate is 3 to 25 cases per 10,000 patient-years of lens wear. None of the subjects presenting with microbial keratitis experienced a permanent decrease of visual acuity of more than two lines.

**Study Strengths**

This was a prospective study that followed a large number of subjects, 6,412, with a wide range of ages over an extended period of time, up to 3.5 years, by a large number of varied Investigators, 158. The study was a surveillance of the performance of the lens in a wide variety of practice settings rather than a controlled clinical trial. The study endpoints were predetermined, easily understood, and well defined, including a detailed definition of microbial keratitis. Incidence rates were based on subjects compliant with the full 30-day wearing period. Cases were classified by experienced clinical researchers.

**Study Limitations**

Prospective surveillance studies are useful in providing estimates of specific risks that occur infrequently; however, there can be limitations. The study was not a controlled trial with rigorous follow-up. The selection of Investigators was open to all practitioners, some of who may not have fully appreciated the commitment of participating in a surveillance study. With this wide variety of Investigators, there was variability in documentation, treatment and subjective language in medical records. Compliance with lens wear requirements was based on periodic reports by subjects. The classification of microbial keratitis was determined by clinical researchers who had direct communication with the Investigator but did not have direct contact with the subject or photographs.

The Study Strengths and Study Limitations should be considered when evaluating the significance of the results.



## SELECTION OF PATIENTS

The eye care practitioner should not fit, or provide lenses to, patients who cannot, or will not, adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses. 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 PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner 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 practitioner.

## 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 post-fitting examination results can be compared.

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



**2. Initial Lens Power Selection**

a. Select the initial trial lens from the Toric Diagnostic Lens Set with a power most similar to the patients' refractive needs, or order a diagnostic lens to the prescription which most closely matches that of the patient.

b. Place the lens on the eye and 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. The toric diagnostic lens is used to optimize lens fitting characteristics and determine axis orientation. Lens power is determined by the spectacle refraction.

- Rotation evaluation: The center guide mark should locate at the inferior limbus. Once oriented, rotational rocking should be limited to less than 5°.
- Movement: The lens should provide discernible movement with:
  - Primary gaze blink
  - Upgaze lag
- Centration: The lens should provide full corneal coverage.

b. Determine contact lens power. When the toric diagnostic lens does not have an equivalent to their spectacle Rx, sphero-cylinder over-refractions will often be inaccurate and confusing. Therefore it is usually preferable to use the spectacle RX as the only basis for the contact lens power. The sphere and cylinder power of the spectacle Rx becomes the sphere and cylinder power of the contact lens. There are two exceptions:

1. If spectacle cylinder power falls between available contact lens cylinder powers, prescribe the lesser contact lens cylinder power. The sphere power can be increased -0.25D to compensate if desired. Of course, this can vary depending on your interpretation of the patient's subjective responses.

   Example: Spectacle Rx: -2.00 -1.00 X 180
   Contact Lens Power Ordered: -2.25 -0.75 X 180

2. When the spectacle lens power in any principal meridian is greater than 4.00D, the spectacle refraction should be vertexed to the corneal plane. This can affect both the sphere and cylinder powers ordered.

   Example: Spectacle Rx: -5.00 -2.75 X 180
   Contact Lens Power Ordered: -4.75 -2.25 X 180



c. Determine contact lens axis. Note the orientation of the guide mark relative to the vertical meridian. Regardless of which eye the lens is on, if the rotation is clockwise but stable, note the amount of rotation, add it to the refractive cylinder axis and order the resulting axis. If the rotation has stabilized counterclockwise, again note the rotation, subtract it from the refractive axis and order the resulting axis. The guide mark can be used to help you calculate the axis of the desired Rx lens.

   Example: Spectacle Rx: -2.50 -1.25 X 80
   Rotation: 20° clockwise
   Final Lens Prescription: -2.50 -1.25 X 100

d. Select patient's lenses.

e. Evaluate orientation of final Rx lenses. The orientation of the prescription should be the same as that observed for the Fitting Set Lenses. For example, if the lens rotated clockwise 15° then the final prescription lens should also rotate clockwise 15°.

**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 that 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.

With your finger, gently rotate the lens approximately 45° to the temporal side. It should reorient within 5 to 10 blinks back to the same stabilized position.

**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.

- 24 hours
- 10 days
- 1 month
- 3 months
- Every 6 months thereafter

At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal and that the adaptation period should be relatively brief. Depending on the patient's prior experience with contact lenses and/or continuous wear, the eye care practitioner may consider prescribing a one week period of daily wear adaptation prior to beginning continuous wear.

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 that might be occurring related to contact lens wear. If the patient is wearing the lenses for continuous wear, the follow-up examination should be conducted as early as possible the morning after overnight wear.

c. With lenses in place on the eyes, evaluate fitting performance to ensure 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.



## PRACTITIONER FITTING SETS

Lenses must be discarded after a single use and must not be used from patient to patient.

## WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, 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 practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

**Continuous Wear (Greater than 24 hours or while asleep):**

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Bausch + Lomb recommends beginning continuous wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of continuous wear one night at a time, unless individual considerations indicate otherwise.

The practitioner should examine the patient in the early stages of continuous 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 practitioner. (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 practitioner.**

## 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 PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lenses.



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 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**

a. Ocular Preference Determination Methods

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

- 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 diopter 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 fingernails. 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 are 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 practitioner in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.**

## LENS CARE

**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 practitioner 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.

For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.

a. **Soaking and Storing Lenses**
***Instruction for Use:***
Use only fresh contact lens disinfecting solution each time you soak (store) lenses.
**WARNING:**
Do not reuse or "top-off" old solution left in lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in the case.



b. **Rub and Rinse Time**
***Instruction for Use:***
Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.
**WARNING:**
• Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.

• **Never use water**, saline solution, or rewetting drops to disinfect lenses. These solutions will not disinfect lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

c. **Lens Case Care**
***Instruction for Use:***
• Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. **Never use water.** Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions **(never use water)** and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.

• Replace lens case according to the directions given by your eye care practitioner or the labeling that came with your case.

• Contact lens cases can be a source of bacterial growth.

**WARNING:**
Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

d. **Water Activity**
***Instruction for Use:***
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 your lenses have been submersed in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing lenses during any activity involving water.



e. **Discard Date on Solution Bottle**
***Instruction for Use:***
Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking contact lenses.
**WARNING:**
Using solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

## CARE FOR A STICKING (NON-MOVING) 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 practitioner 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 practitioner.

## EMERGENCIES

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

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb PureVision®2 For Astigmatism (balafilcon A) 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 US, Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000 (Option 9 - French)



## HOW SUPPLIED

Each sterile lens is supplied in a plastic blister package containing borate buffered saline solution that may contain poloxamine 1107. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, cylinder power, axis, diameter, and expiration date. Store lenses at room temperature of 15° to 25°C (59° to 77°F).

PACKAGE INSERT / FITTING GUIDE

BAUSCH+LOMB PureVision®2 (balafilcon A)

# Visibility Tinted Contact Lenses

## For Presbyopia

℞ ONLY **CAUTION:** Federal law restricts this device to sale by or on the order of a licensed practitioner.



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

Printed in the USA

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8128803

## SYMBOL REFERENCE GUIDE

For label and cartons:

The following symbol is for the CE Quality Certification
CE 0050

Meets EU Packaging Directive

STERILE — Sterilized using steam

Caution

DIA $Ø_T$ — Diameter

EXP — Use-by date

LOT — Batch code

EC REP — Authorized representative in the European Community

℞ ONLY — Prescription only (USA)

PWR $F'_V$ — Power

BC — Base curve

ADD — Add power

Temperature limit

YYYY-MM-DD — Effective date

Manufacturer

8128803

## TABLE OF CONTENTS



## IMPORTANT

This package insert and fitting guide has been developed to provide professionals with information covering characteristics of the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens and to illustrate fitting procedures. It is effective as of the date on the 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 practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens and the recommended wearing schedule.



## DESCRIPTION

The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens is a soft hydrophilic contact lens that is a front surface asphere consisting of multiple aspheric zones with a spherical base curve. The most plus power is in the center of the lens, progressing to more minus in the periphery. The lens material, balafilcon A, is a copolymer of a silicone vinyl carbamate, N-vinyl-pyrrolidone, a siloxane crosslinker and a vinyl alanine wetting monomer, and is 36% water by weight when immersed in a sterile borate buffered saline solution. This lens is tinted blue with up to 300 ppm of Reactive Blue Dye 246.

The physical / optical properties of the lens are:

| | |
|---|---|
| Specific Gravity: | 1.064 |
| Refractive Index: | 1.426 |
| Light Transmittance: | C.I.E. value—at least 95% |
| Water Content: | 36% |
| Oxygen Permeability: | $91 \times 10^{-11}$ [$cm^3O_2$(STP) x cm]/(sec x $cm^2$ x mmHg) @ 35°C Polarographic Method (Boundary and Edge Corrected) |
| | $101 \times 10^{-11}$ [$cm^3O_2$(STP) x cm]/(sec x $cm^2$ x mmHg) @ 35°C Polarographic Method (Boundary Corrected, Non-Edge Corrected) |

The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens, with AerGel™ technology lens material, are manufactured by a cast molding process and are treated by the Performa™ surface treatment process which transforms hydrophobic silicone to hydrophilic silicate. The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens may be prescribed for Frequent/Planned Replacement or Disposable Wear.

## LENS PARAMETERS AVAILABLE

The Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

| | |
|---|---|
| Diameter: | 14.0mm |
| Center Thickness: | Varies with power (0.070mm at -3.00D) |
| Base Curve: | 8.6mm |
| Powers (Spherical): | +6.00D to -10.00D in (0.25D increments) (0.50D steps above -6.00)* |
| Add Powers: | Low (+0.75D to +1.50D) and High (+1.75D to +2.50D) |

*Additional powers may be introduced over time, check for product availability.



## HOW THE LENS WORKS (ACTIONS)

In its hydrated state, the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) 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 PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 30 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 2.00 diopters, that does not interfere with visual acuity. The lens may be prescribed for Frequent / Planned Replacement Wear or Disposable Wear in spherical powers ranging from +6.00D to -18.00D when prescribed for up to 30 days of extended wear and from +20.00D to -20.00D for daily wear or extended wear up to 7 days with add powers ranging from +0.75D to +5.00D.

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

**FREQUENT / PLANNED REPLACEMENT WEAR**

When prescribed for Frequent / Planned Replacement Wear, the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) 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 practitioner. The lens may be disinfected using a chemical disinfection system.

**DISPOSABLE WEAR**

When prescribed for Disposable Wear, the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) 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 PureVision®2 For Presbyopia (balafilcon A) 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 practitioner'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 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.

**EXTENDED WEAR**

- The risk of microbial 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 endothelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.
- The risk of microbial keratitis has not been determined for this lens. A post-approval study with average follow-up of 15 months has been completed.
- The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, professionals' views of extended wearing times 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 30 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses and promptly contact his or her eye care practitioner.**

## PRECAUTIONS

**Precautions for Eye Care Practitioners**

- 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 practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.
- The oxygen transmissibility is below the established threshold required to prevent overnight corneal edema for portions of the power range, including plus powers and some low minus power lenses.[1] In the US clinical study of the PureVision (spherical) lens, the rate of infiltrative keratitis was found to be higher with higher lens powers (see Clinical Studies section of the package insert).
- 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 practitioner should carefully monitor the continuing ocular health of the patient and lens performance on eye.
- Patients who wear aspheric contact lenses, such as the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens, 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.

[1] *Holden BA, Mertz GW. Critical Oxygen Levels to Avoid Corneal Edema for Daily and Extended Wear Contact Lenses. Invest Ophthalmol Vis Sci 25:1162, 1984.*



- Eye care practitioners 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 practitioner.
- Some patients will not be able to tolerate continuous wear even if able to tolerate the same or another lens on a daily wear basis. Some patients who are able to tolerate continuous wear will not be able to wear their lenses continuously for 30 days. Patients should be carefully evaluated for continuous wear prior to prescription and dispensing, and eye care practitioners should conduct early and frequent follow-up examination to determine ocular response to continuous 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.
- Aphakic patients should not be fitted with Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses until the determination is made that the eye has healed completely.

Eye care practitioners 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 PureVision®2 For Presbyopia (balafilcon A) 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-based cosmetics are less likely to damage lenses than oil-based products.
- Be sure that before leaving the eye care practitioner'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 PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens and those prescribed by the eye care practitioner.
- 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**

**Do not use the Ultracare Disinfecting System or any of its components (Ultracare Disinfecting Solution, Ultracare Neutralizing Tablets, Lens Plus Daily Cleaner, and Ultrazyme Enzymatic Cleaner) to clean and disinfect the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens because the lens dimensions will be altered.**

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 practitioner.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- 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 practitioner.

**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 practitioner 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 the lenses.**
- If the discomfort or problem stops, the patient should look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on the eye. The patient should place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, 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 his or her eye care practitioner.**

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 practitioner** 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 staining 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.

## CLINICAL STUDIES

The following clinical results are provided for informational purposes. It is important to note that the results below are from studies conducted with the Bausch + Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lens which has the same lens material, but different lens design. These studies were conducted with subjects not requiring presbyopic correction.

**PRE-APPROVAL EXTENDED WEAR STUDIES**

**STUDY DESCRIPTION**

**Study Design**

The objective of this 12-month study was to evaluate the safety and efficacy of the PureVision® (balafilcon A) Visibility Tinted Contact Lenses worn on a 30-day continuous wear basis, compared to a conventional control lens worn on a 7-day continuous wear basis. A total of 1640 eyes (820 subjects) were enrolled into this study. Subjects were fitted with a PureVision® Contact Lens on one eye while the contralateral eye was fitted with a control lens. Subjects were instructed to replace the PureVision® Contact Lens with a new lens every 30 days, and to wear the control lens overnight for up to six consecutive nights per week. Eyes had one night without lens wear after the scheduled removal. The control lens was to be replaced with a new lens every 14 days.

Six hundred ten (610) subjects completed the one-year study. Ten subjects discontinued in the daily wear adaptation period, 182 subjects discontinued during the extended wear phase and 18 subjects were not dispensed lenses.



**Patient Assessments**

Subjects were evaluated at follow-up visits scheduled after 24 hours, 10 days, 1 month, 3 months, 6 months, 9 months, and 12 months of lens wear.

**Demographics**

Subject recruitment was open to adapted and unadapted contact lens wearers. There were no restrictions as to the subject's gender or occupation, but subjects were required to be of legal age (typically 18 or 21) and have the legal capacity to volunteer. The ages of the subjects ranged from 18 to 74 years of age, with a mean age of 33.6, and included 574 females and 228 males, with a ratio of 2.52 females to every male. For the PureVision® Contact Lens the power range used was -0.50D to -9.00D. For the control lens the power range was -0.50D to -8.50D.

The previous lens wearing experience of the subjects that participated in the study was 5% no lens wear, 43% daily wear, and 51% continuous wear. The refractive errors of the subjects ranged from -0.25D to -11.75D, and included up to -2.00D of astigmatism.

**SUMMARY OF DATA ANALYSES**

**Summary of Data Analyses**

The key endpoints for this study were:

1. Grade 2 and higher slit lamp findings (safety endpoint),
2. Grade 2 and higher corneal infiltrates (safety endpoint), and
3. Contact lens corrected visual acuity worse than 20/40 (efficacy endpoint).

For each key endpoint, the rates (incidents of endpoint/number of eyes) experienced by eyes in the PureVision® Contact Lens and control lenses were calculated. The difference in rates between the two lens types was determined and a 95% confidence interval for the difference was calculated. For each key endpoint a "clinically significant difference" in the rates was established before the study started. These "clinically significant differences" were as follows: 10% for total slit lamp findings ≥Grade 2, 5% for corneal infiltrates ≥ Grade 2, and 5% for the acuity endpoint. For example, if the true rates of endpoint infiltrates in the subject population were 9.9% in the PureVision® Contact Lens and 5% in the control lens, these rates would be considered substantially equivalent (difference <5%).

In order to be successful for a given endpoint, the upper 95% confidence limit for the difference in the study rates had to be less than the pre-established "clinically significant difference." This means that we are 95% confident that the true difference is within tolerance. The safety and efficacy goals were met for all three key endpoints. Results are as follows:



| | PureVision | | Control | | Relative Risk/ PureVision Control | Difference in % | Upper 95% Confidence Level | Clinically Significant Difference |
|---|---|---|---|---|---|---|---|---|
| Endpoint | n | % | n | % | | | | |
| Slit Lamp Findings ≥ Grade 2 | 138 | 17.5% | 139 | 17.6% | 1.0 | -0.1% | 2.6% | 10.0% |
| Corneal Infiltrates ≥ Grade 2 | 23 | 2.9% | 10 | 1.3% | 2.3 | 1.6% | 2.9% | 5.0% |
| Visual Acuity Worse than 20/40 | 0 | 0.0% | 2 | 0.3% | 0.0 | -0.3% | 0.1% | 5.0% |

**Summary of Slit Lamp Findings**

Slit lamp examinations were conducted at every study visit. Each graded slit lamp parameter was scored on a qualitative grade scale ranging from 0 to 4, with Grade 0 representing the absence of findings, and Grades 1 through 4 representing successively worse findings. For each study eye, a determination was made for each parameter as to whether, or not a positive finding was presented at any visit. The following table describes slit lamp findings ≥ Grade 2 and ungraded slit lamp findings.



| | PureVision | Control |
|---|---|---|
| Graded Slit Lamp Findings (≥ Grade 2) | | |
| **Any Finding**[1,2] | **17.5%** | **17.6%** |
| Corneal Staining | 8.2% | 8.4% |
| Limbal Injection | 3.7% | 4.3% |
| Bulbar Injection | 5.2% | 4.7% |
| Tarsal Conjunctival Abnormalities | 3.9% | 3.9% |
| **Corneal Infiltrates**[1] | **2.9%** | **1.3%** |
| Epithelial Edema | 1.3% | 1.4% |
| Epithelial Microcysts | 1.0% | 1.0% |
| Corneal Neovascularization | 1.0% | 1.7% |
| Ungraded Slit Lamp Findings | | |
| Other Anterior Segment Abnormalities[3] | 13.2% | 13.8% |
| External Adnexa Abnormalities | 2.7% | 2.7% |
| Conjunctivitis | 2.4% | 2.0% |
| Corneal Striae | 0.0% | 0.3% |

[1] Slit Lamp Finding and Corneal Infiltrates ≥ Grade 2 were the safety endpoints for this study.
[2] The total of all Graded slit lamp findings does not equal the category of Any Finding.
[3] The more common findings identified as Other Anterior Segment Abnormalities included: conjunctival staining; dimple veils; mucin balls; lipid deposits; and ghost vessels.

It should be noted that the PureVision® Contact Lens and the control lens were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.

**Corneal Infiltrates**

The following table describes the rate of corneal infiltrates according to the lens power used.

| | Lens Power | Corneal Infiltrates (≥ Grade 2) |
|---|---|---|
| PureVision | Plano to - 3.00 | 1.7 % |
| | - 3.25 to - 6.00 | 3.2 % |
| | > - 6.00 | 6.4 % |
| | Total | 2.9 % |

| | Lens Power | Corneal Infiltrates (≥ Grade 2) |
|---|---|---|
| Control | Plano to - 3.00 | 0.9 % |
| | - 3.25 to - 6.00 | 1.5 % |
| | > - 6.00 | 1.3 % |
| | Total | 1.3 % |

**Other Lens-Related Adverse Events**

In addition to the outcomes described above, the following lens related adverse events were noted. This table does not include conjunctivitis or tarsal conjunctival abnormalities, e.g., giant papillary conjunctivitis.

**Other Important Lens-Related Adverse Events**

| | PureVision | Control |
|---|---|---|
| Corneal Scar | 14 (1.8 %) | 5 (0.6 %) |
| Other Ocular Inflammation* | 10 (1.3 %) | 2 (0.3 %) |
| Anterior Chamber Reaction | 2 (0.3 %) | 1 (0.1 %) |
| Permanent Loss of Vision | 0 (0.0 %) | 0 (0.0 %) |

* Other Ocular Inflammation includes episcleritis, scleritis, iritis/uveitis. This condition was reported in association with other conditions such as keratitis, corneal infiltrates, blepharitis, corneal abrasion, and contact lens over wear.



It should be noted that the PureVision® Contact Lens and control lenses were each fit on only the right or left eye for each subject. Rates per subject are expected to be higher when lenses are fit on both eyes.

**Efficacy Outcomes**

The contact lens visual acuity was measured at each scheduled and unscheduled follow-up visit throughout the one-year study. For the 610 subjects that completed the study, visual acuity of 20/20 or better was reported for 87% and 86% of the measurements for the PureVision® Contact Lens and control lens, respectively. Similarly, visual acuity of 20/25 or better was reported 98% and 97% of the times for the PureVision® Contact Lens and control lens.

**Wearing Time**

In this US clinical study subjects were required to maintain a minimum wearing time in order to continue in the study. For the subjects that completed the study, the average continuous wear time for the PureVision® Contact Lens was at least 28.0 days per month, from the 2-Month visit through the 12-Month visit. At these visits the same subjects reported they were able to wear the PureVision® Contact Lens at least 22 days continuously 94% of the times they were asked.

During the course of the study, 15 subjects were discontinued from the study because they were not able to wear the PureVision® Contact Lens for 30 days. Twenty-one (21) subjects were discontinued from the study because they were not able to wear the control lens for 7 days.

**Overnight Corneal Swelling**

Two separate studies with the PureVision® Lens (spherical) assessed the corneal swelling response induced by overnight contact lens wear. In the first study, 30 subjects each wore either a +3.00D, -3.00D, or -9.00D PureVision® Contact Lens and an equivalent power lens made from a conventional hydrogel material (control lens) on the contralateral eye overnight under closed eye conditions for approximately eight hours. The corneal swelling, measured as the percent increase in the center thickness of the cornea, with the control lens (9.1%) was significantly greater than that measured in conjunction with the PureVision® Contact Lenses (4.1%). In the second study, the corneal swelling response was measured under similar conditions. In this study, the response to a -3.00D PureVision® Contact Lens (3.0%) was compared to the swelling response to no lens wear (1.9%). The responses were not statistically different (p-value > 0.05).

**POST-APPROVAL EXTENDED WEAR STUDY**

The purpose of this post-approval study was to investigate the occurrence of serious adverse events with the PureVision® Contact Lens when worn on a 30-day continuous wear basis. Serious adverse events were any case of microbial keratitis (infected corneal ulcer) or a loss of more than two lines of best corrected visual acuity.



**Study Design**

The intent of the study was to enroll up to 6,500 subjects who would account for 4,500 to 5,000 subject-years of lens wear enrolled by a minimum of 100 Investigators. Study lenses were dispensed to 6,412 subjects who provided 5,054 patient-years of compliant wear while being followed by 158 Investigators. The age of the eligible subjects dispensed study lenses ranged from 12 to 85, with a mean age of 36 years and a ratio of 1.74 female subjects for every male. The spherical refractive error of subjects ranged from +10.00D to -15.00D with a mean of -3.4D.

A subject was eligible for entry into the study if the subject:

1. was, in the opinion of the Investigator, suitable for continuous soft contact lens wear;
2. agreed to wear lenses on a 30-day continuous wear basis; and
3. was age 12 or older.

The study protocol did not define exclusion criteria. Subjects that in the opinion of the Investigator were not suitable for continuous wear were excluded from the study. The Investigators were not required to describe preexisting conditions that precluded enrollment.

The study was divided into two phases: Phase 1 lasted for approximately 12 months; Phase 2 was considered optional and consisted of the duration of time a subject was in PureVision lenses following completion of Phase 1. The maximum length of Phase 2 was 3 years.

In both phases, each subject wore a PureVision® Contact Lens on each eye on a 30-day continuous wear basis. Lenses were worn overnight without removal for 22-29 consecutive nights, and were removed and replaced with new lenses on the morning of the 30th day.

Follow-up visits were scheduled at 6-month intervals following the Enrollment Visit. At the Enrollment Visit and at all scheduled and unscheduled Follow-Up visits, the Investigator evaluated the best corrected spherocylindrical refractive visual acuity and examined the subject for corneal scarring and/or indications of microbial keratitis. The subjects were also questioned regarding their compliance with the lens wear schedule.

The last scheduled follow-up visit during Phase 2 was the 48-Month Visit. If a subject exited the study in Phase 2 before the 48-Month Visit, the subject was considered completed, if he/she completed a 12-Month Visit or later. The duration of the study extended until the time that the last subject enrolled had completed 12 months of contact lens wear in Phase 1.

All reports of possible microbial keratitis, any report by a clinical investigator of the presence of a new corneal scar or other indication of microbial keratitis, were subjected to a multi-stage evaluation process. A thorough case review for all reports of new corneal scars or other indications of microbial keratitis was completed by a Bausch + Lomb clinician who eliminated cases with clear evidence refuting a microbial keratitis diagnosis.



Then a panel of three Bausch + Lomb clinicians reviewed each of the remaining cases, and compared the clinical findings to the study definition of microbial keratitis. The records of the suspect microbial keratitis cases, the opinions and diagnosis of the independent Clinical Investigator and information from any other treating physician were reviewed by the panel and Bausch + Lomb Chief Medical Officer for a final determination.

**Results**

Of the 6,412 subjects dispensed study lenses, there were 7 cases of microbial keratitis reported for 7 individual subjects. No subject was diagnosed with microbial keratitis in both eyes. The table below presents a summary of the occurrence rates for microbial keratitis, new corneal scars or other indication of microbial keratitis, or permanent decrease in visual acuity of 2 or more lines.

| | Cases | Patient-Years | Annual Incidence* | 95%CI* |
|---|---|---|---|---|
| **Microbial Keratitis** | | | | |
| **All Years** | 7 | 5054 | 13.9 | (3, 25) |
| **First Year** | 7 | 3779.5 | 18.5 | (3, 34) |
| **New Corneal Scar or Other Reports Suggestive of Microbial Keratitis** | | | | |
| **All Years** | 35 | 5154.5 | 67.9 | (45, 91) |
| **First Year** | 34 | 3843 | 88.5 | (58, 119) |
| **Permanent Decrease in Visual Acuity of 2 or More Lines** | | | | |
| All Years | 0 | 5054 | 0 | (0, 0.98) |
| First Year | 0 | 3779.5 | 0 | (0, 1.3) |

*/ Per 10,000 patient-years*

Patient-years were calculated considering various periods of compliant lens wear. The subjects that wore their lenses, on average, for 3 weeks out of each 4-week period, for all periods of wear contributed 5,054 patient-years of wear. With 7 cases of microbial keratitis for 5,054 patient-years, the incidence of microbial keratitis is 13.9 cases per 10,000 patient-years of lens wear.

The total wear time for compliant subjects over the first year of participation in the study contributed 3779.5 patient-years of wear. This results in an incidence of microbial keratitis of 18.5 cases per 10,000 patient-years of lens wear.



There were no confirmed cases of a permanent best corrected visual acuity decrease of more than two lines related to lens wear including the 7 subjects that presented with microbial keratitis. Fifteen subjects were reported to have a best corrected visual acuity decrease of more than two lines during all periods of compliant lens wear that were classified as not lens related. Reasons for these decreases in vision included a retinal hemorrhage, retinal detachments and cataracts.

**Conclusions**

The incidence of microbial keratitis associated with 30 days of continuous wear of PureVision® Contact Lenses was 13.9 cases per 10,000 patient-years of lens wear. The 95% confidence interval around this estimate is 3 to 25 cases per 10,000 patient-years of lens wear. None of the subjects presenting with microbial keratitis experienced a permanent decrease of visual acuity of more than two lines.

**Study Strengths**

This was a prospective study that followed a large number of subjects, 6,412, with a wide range of ages over an extended period of time, up to 3.5 years, by a large number of varied Investigators, 158. The study was a surveillance of the performance of the lens in a wide variety of practice settings rather than a controlled clinical trial. The study endpoints were predetermined, easily understood, and well defined including a detailed definition of microbial keratitis. Incidence rates were based on subjects compliant with the full 30-day wearing period. Cases were classified by experienced clinical researchers.

**Study Limitations**

Prospective surveillance studies are useful in providing estimates of specific risks that occur infrequently; however, there can be limitations. The study was not a controlled trial with rigorous follow-up. The selection of Investigators was open to all practitioners, some of who may not have fully appreciated the commitment of participating in a surveillance study. With this wide variety of Investigators, there was variability in documentation, treatment and subjective language in medical records. Compliance with lens wear requirements was based on periodic reports by subjects. The classification of microbial keratitis was determined by clinical researchers who had direct communication with the Investigator, but did not have direct contact with the subject or photographs.

The Study Strengths and Study Limitations should be considered when evaluating the significance of the results.

## SELECTION OF PATIENTS

The eye care practitioner should not fit, or provide lenses to, patients who cannot, or will not, adhere to a recommended care or replacement regimen, or are unable to place and remove the lenses. 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 PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner 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 practitioner.

## 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 post-fitting examination results can be compared.

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

**2. Lens Selection**

a. Update spectacle refraction and Add power.

b. Determine ocular dominance for distance vision.

c. Select lens distance prescription based upon spherical equivalent from spectacle prescription, adjusted for vertex distance if necessary.

d. Choose trial lenses based upon the above calculation and select Add power.
   - Bausch + Lomb PureVision®2 for Presbyopia Low Add: +0.75D to +1.50D
   - Bausch + Lomb PureVision®2 for Presbyopia High Add: +1.75D to +2.50D



**3. Lens Fitting**

a. Allow lens to equilibrate for at least 10 minutes before assessing fit and vision.

b. Evaluate distance and near vision binocularly in normal room illumination.

c. If vision at distance and near are satisfactory, dispense lenses and schedule follow-up exam within 1-2 weeks.

**4. To Refine Near Vision**

If patient is wearing two Low Add lenses:

- Refinement 1:

  Place Bausch + Lomb PureVision®2 for Presbyopia High Add in non-dominant eye while keeping Bausch + Lomb PureVision®2 for Presbyopia Low Add in dominant eye.

- Refinement 2:

  If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:

  Add +0.25D to the non-dominant eye.

- Refinement 2:

  If vision is still unsatisfactory, continue adding +0.25D at a time to the non-dominant eye using handheld lenses.

**5. To Refine Distance Vision**

If patient is wearing two Low Add lenses:

- Refinement 1:

  Fit Bausch + Lomb PureVision®2 for Presbyopia in dominant eye while keeping Bausch + Lomb PureVision®2 for Presbyopia Low Add in non-dominant eye.

- Refinement 2:

  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision is satisfactory.

If patient is wearing two High Add lenses:

- Refinement 1:

  Fit with Bausch + Lomb PureVision®2 for Presbyopia Low Add in dominant eye while keeping Bausch + Lomb PureVision®2 for Presbyopia High Add in non-dominant eye.

- Refinement 2:

  If vision is still unsatisfactory, add -0.25D at a time to dominant eye using hand held lenses. Adjust contact lens power when vision is satisfactory.



**6. 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, the lens should not be dispensed. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, the lens should not be dispensed.

**7. 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.

**8. 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.

**9. 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.



**10. 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.
   - 24 hours
   - 10 days
   - 1 month
   - 3 months
   - Every six months thereafter

   At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief. Depending on the patient's prior experience with contact lenses and/or continuous wear, the eye care practitioner may consider prescribing a one week period of daily wear adaptation prior to beginning continuous wear.

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. If the patient is wearing the lenses for continuous wear, the follow-up examination should be conducted as early as possible the morning after overnight 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.



**11. Patient Education**

All patients do not function equally well with multifocal correction. Patients may not perform as well for certain tasks with this correction as they have with multifocal reading glasses. Each patient should understand that multifocal correction 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 multifocal contact lenses provide.

## PRACTITIONER FITTING SETS

Lenses must be discarded after a single use and must not be used from patient to patient.

## WEARING SCHEDULE

The wearing and replacement schedules should be determined by the eye care practitioner. Regular checkups, as determined by the eye care practitioner, 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 practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

**Continuous Wear (Greater than 24 hours or while asleep):**

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgment. Bausch + Lomb recommends beginning continuous wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of continuous wear one night at a time, unless individual considerations indicate otherwise.

The practitioner should examine the patient in the early stages of continuous 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 practitioner. (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 practitioner.**



## 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 PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lenses.

   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 multifocal reading glasses. Each patient should understand that monovision 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**

a. Ocular Preference Determination Methods
   Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.
   - 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 diopter 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 fingernails. 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 are 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 practitioner in conjunction with the patient after carefully considering the patient's needs.**
- **All patients should be supplied with a copy of the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.**

## LENS CARE

**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 practitioner 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.

For complete information concerning the care, cleaning and disinfection of contact lenses refer to the Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.

a. **Soaking and Storing Lenses**
   ***Instruction for Use:***
   Use only fresh contact lens disinfecting solution each time you soak (store) lenses.

   **WARNING:**
   Do not reuse or "top off" old solution left in lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness. "Topping-off" is the addition of fresh solution to solution that has been sitting in the case.

b. **Rub and Rinse Time**
   ***Instruction for Use:***
   Follow the complete recommended lens rubbing and rinsing times in the labeling of the solution used for cleaning, disinfecting and soaking lenses to adequately disinfect lenses and reduce the risk of contact lens infection.



**WARNING:**

• Rub and rinse lenses for the recommended amount of time to help prevent serious eye infections.

• **Never use water**, saline solution, or rewetting drops to disinfect lenses. These solutions will not disinfect lenses. Not using the recommended disinfectant can lead to severe infection, vision loss or blindness.

c. **Lens Case Care**
   ***Instruction for Use:***
   • Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/ contact lens cleaner. **Never use water.** Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions **(never use water)** and wiping the lens cases with fresh, clean tissue is recommended. Never air-dry or recap the lens case lids after use without any additional cleaning methods. If air-drying, be sure that no residual solution remains in the case before allowing it to air-dry.

   • Replace lens case according to the directions given by your eye care practitioner or the labeling that came with your case.

   • Contact lens cases can be a source of bacterial growth.

   **WARNING:**
   Do not store lenses or rinse lens case with water or any non-sterile solution. Only use fresh solution so you do not contaminate lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

d. **Water Activity**
   ***Instruction for Use:***
   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 your lenses have been submersed in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask your eye care practitioner (professional) for recommendations about wearing lenses during any activity involving water.

e. **Discard Date on Solution Bottle**
   ***Instruction for Use:***
   Discard any remaining solution after the recommended time period indicated on the bottle of solution used for disinfecting and soaking contact lenses.

   **WARNING:**
   Using solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.



## CARE FOR A STICKING (NON-MOVING) 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 practitioner 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 practitioner.

## EMERGENCIES

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

## REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Bausch + Lomb PureVision®2 For Presbyopia (balafilcon A) 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 US, Alaska, Hawaii
1-800-553-5340
In Canada
1-888-459-5000 (Option 1 - English, Option 2 - French)

## HOW SUPPLIED

Each sterile lens is supplied in a plastic blister package containing borate buffered saline solution which may contain poloxamine 1107. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, add power, diameter and expiration date. Store lenses at room temperature 15° to 25°C (59° to 77°F).