



# Bausch & Lomb PureVision® (balafilcon A)

Visibility Tinted Contact Lenses

PATIENT INFORMATION BOOKLET



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

Store lenses at room temperature 59° to 77°F (15° to 25°C).



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# INTRODUCTION

The instructions in this booklet apply to the Bausch & Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lenses. If you have received or are considering another brand of contact lenses, do not use this booklet. Ask your eye care practitioner for the patient booklet or instructions that apply to your brand or type of contact lenses. For PureVision® Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care practitioner answer any questions, both before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to begin or to continue wearing contact lenses for daily wear or continuous wear, you should discuss with your eye care practitioner the effects of contact lenses on your eyes and the risks associated with wearing contact lenses, which are greater with continuous wear contact lens use. You also should read the sections of this booklet entitled "Warnings", "Adverse Reactions", "Precautions", and "Wearing Restrictions and Indications". Ask your eye care practitioner to explain anything that you do not understand, including any additional restrictions which may be given to you by your eye care practitioner.

You also need to remember that soft contact lenses, including those covered by this booklet, are made of a type of plastic that absorbs liquids, vapors, and small particles, and, for some people, may collect deposits from your natural eye fluids. Therefore, you should strictly follow the instructions contained in the sections of this booklet entitled "Personal Cleanliness and Lens Handling", as well as the written information leaflets accompanying the lens care products that you buy and any other instructions given to you by your eye care practitioner. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a build-up of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule and replacement schedule, and regular check-up visits to your eye care practitioner are also necessary for the proper and safe use of contact lenses.

**It is important to not wear your lenses longer than recommended by your eye care practitioner since doing so increases the risk of adverse effects.**

Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not wear your lenses for longer periods than your prescribed wearing schedule simply because they remain comfortable and you are not experiencing a problem. Only your eye care practitioner, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

If problems or symptoms should occur, immediately remove your lenses and follow the steps described in the section of this booklet entitled "Warnings" and "Adverse Reactions". (Refer to "Glossary of Medical Terms" for description of medical terms used in this booklet). Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

# WEARING RESTRICTIONS AND INDICATIONS

## VISION CORRECTION

The Bausch & Lomb PureVision® (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 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® (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® (balafilcon A) Visibility Tinted Contact Lenses 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.

PureVision® 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 PureVision® 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 PureVision® Contact Lens is to be discarded after each removal.

## WEARING RESTRICTIONS

The PureVision® Contact Lenses described in this booklet should be removed from your eyes for routine cleaning and disinfecting as prescribed by your eye care practitioner.

**For extended wear, once the lenses are removed, your eyes should have a rest without lens wear for at least one overnight, as recommended by your eye care practitioner.** Your eye care practitioner will tell you how long to rest your eyes in between wearing periods and will also recommend a replacement period and appropriate lens care products.

## CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the Bausch & Lomb PureVision® (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 PureVision® Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

## WARNINGS

You should be aware of and fully discuss with your eye care practitioner the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to your eye. It is essential that you follow your 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**.
- Strict compliance with your lens care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be followed.
- 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 continuous 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, continuous 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 continuous wear. The epithelial conditions are reversible upon discontinuation of continuous 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 continuous wearing times vary from not prescribing continuous wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing continuous 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 you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should immediately remove lenses and promptly contact your eye care practitioner.

## PRECAUTIONS

You should be aware of and fully discuss with your eye care practitioner the following lens care regimen and safety precautions:

### SPECIFIC PRECAUTIONS

- Always discard disposable lenses and lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by the eye care practitioner.

### 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.
- Before leaving your eye care practitioner's office be certain that you are able to remove your lenses promptly or have someone else available to remove them for you.
- Be certain that the fingers or hands are free of foreign materials before touching your lenses, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Always handle your lenses carefully and avoid dropping them.
- Do not touch the lens with your fingernails.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eye care practitioner.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.

## IN ADDITION, FOR THERAPEUTIC USE

- Close professional supervision is necessary for therapeutic use of PureVision® lenses.
- Medications necessary for treatment should be used with caution under close supervision by the eye care practitioner.
- 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 PureVision® Contact Lenses because the lens dimensions will be altered.**

*NOTE: 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.*

- 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 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 your lenses beyond the period recommended by your eye care practitioner. 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.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking (Non-Moving) Lens. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should **immediately** consult your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when 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 monthly intervals as recommended by the lens case manufacturer or eye care practitioner.

## TOPICS TO DISCUSS WITH THE EYE CARE PRACTITIONER

- As with any contact lens, follow-up visits are necessary to assure the continuing health of the eyes. You 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 your eye care practitioner before using any medicine in the eyes.

## WHO SHOULD KNOW THAT THE PATIENT IS WEARING CONTACT LENSES

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

Ask your eye care practitioner whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

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## ADVERSE REACTIONS (PROBLEMS AND WHAT TO DO)

You should be aware 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 you notice any of the above:

- **Immediately remove your lenses.**
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, **do not** put the lens back on your eye. Place the lens in the storage case and contact your 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, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, you should **immediately remove the lenses and consult your eye care practitioner.**

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should **keep the lens off your eye and seek immediate** professional identification of the problem and prompt treatment to avoid serious eye damage.

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

### PRE-APPROVAL EXTENDED WEAR STUDY STUDY DESCRIPTION

A 12-month clinical study of the Bausch & Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lenses showed the lens is safe and effective for vision correction for up to 30 days of continuous wear.

A total of 820 subjects were enrolled in the clinical study. Six hundred ten (610) subjects completed the one-year study. Subjects were fitted with a PureVision® Contact Lens on one eye and a control lens the other eye. 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.

### STUDY RESULTS

All predetermined safety and efficacy study endpoints were successfully achieved. The study showed the PureVision® Contact Lenses, when worn on a 30-day continuous wear basis, is equivalent in safety and efficacy to the control lens when worn on a 7-day continuous wear basis.

### SAFETY

There were no reports of permanent loss of vision for either the PureVision® Contact Lenses or the control lenses. Of the subjects that entered into the continuous wear phase of the study, 2.9% developed corneal infiltrates of the severity identified in the study protocol as a study safety endpoint in the eye containing the PureVision® Contact Lens, compared to 1.3% in the control eyes. It should be noted that the PureVision® Contact Lens and 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.

Other reported adverse events included corneal scars, keratitis, conjunctivitis, ocular infections, and inflammatory reactions. Subjects reported other less serious problems such as dryness, discomfort, and burning and stinging. These symptoms were reported at equivalent rates for the PureVision® Contact Lens and the control lens.

### EFFECTIVENESS

Not all of the subjects were able to wear their lens for the maximum 30-day period. In this U.S. clinical study subjects were required to maintain a minimum wearing time in order to continue in the study. Some subjects were discontinued from the study because they were not able to wear the PureVision® Contact Lens for 30 days.

For the subjects that completed the study, the average continuous wear time for the PureVision® Contact Lens was 28.0 days per month. 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.

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% of the measurements for the PureVision® Contact Lens. Similarly, visual acuity of 20/25 or better was reported 98% of the time.

### POST-APPROVAL EXTENDED WEAR STUDY

The purpose of the post-approval study was to investigate the occurrence of serious adverse events with PureVision® Contact Lenses 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, that is the loss of the ability to read two sizes of letters on the eye chart when corrected with glasses, if needed.

The study analyzed the results of 6,412 patients that accounted for 5,054 patient-years of compliant lens wear. 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. A statistical analysis of the data based on 95% confidence determined this rate could range between 3 and 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.

### THERAPEUTIC USE STUDIES STUDY DESCRIPTION

Two prospective open-ended non-randomized clinical trials were conducted to evaluate PureVision® Contact Lenses as continuous wear lenses for therapeutic indications. The studies included patients who presented at the two centers requiring continuous lens wear for relief of corneal pain, corneal protection, and a bandage during the healing process of certain corneal conditions. Included were treatments for bullous keratopathy, recurrent epithelial erosion, corneal perforations, corneal lacerations, filamentary keratitis, post-keratoplasty, neurotrophic keratitis and ulcer, irregular cornea, dry eye, and ptosis following surgery. Additionally, PureVision® Contact Lenses were applied as post-surgical treatment after refractive laser assisted in-situ keratomileusis (LASIK), photorefractive keratectomy (PRK), phototherapeutic keratoplasty (PTK), and penetrating keratoplasty (PK).

## RESULTS

A total of 84 eyes of 82 subjects from both studies were reported where the average wearing time of the PureVision® Contact Lens was nearly 30 days continuous wear. In the first study, a high degree of success was achieved in the treatment of numerous conditions of corneal disease. Total success was achieved in 83% (33/40) cases and partial success in 96% (38/40) cases for corneal healing; 96% (27/28) and 4% (1/28) of cases for total and partial corneal pain relief; and 100% (21/21) of cases for corneal protection in one study. Included in these data was use of the lens in 10 cases of LASIK, PTK, and superficial keratectomy for treatment of corneal pain relief (10/10), corneal healing (10/10) and corneal protection (6/10). Complications relating to contact lens wear was limited to one case of a corneal infiltrate requiring cessation of lens wear, and one case of a loosely fit lens.

In the second study, a total of 83.3% (26/30) cases achieved therapeutic success overall. However, all subjects reported symptomatic relief. The most common cause of therapeutic failure was due to dry eye. Complications included loss of lenses (2 eyes), tight lens (1 eye) and infective keratitis (2 eyes).

## PERSONAL CLEANLINESS AND LENS HANDLING

### 1. PREPARING THE LENS FOR WEARING

It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.

Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

### 2. HANDLING THE LENSES

- Develop the habit of always working with the same lens first to avoid mix-ups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly.
  - a. Less than usual comfort
  - b. The lens may fold on the eye
  - c. Excessive lens movement on blink
  - d. Blurred vision
- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with the recommended rinsing or storing solution. (Refer to the Lens Care Products Chart for the solutions available from Bausch + Lomb.) Then GENTLY rub the lens between

your index finger and palm in a gentle back and forth motion.

- If this gentle rubbing does not work, soak the lens in the recommended solution in your lens case until the lens has resumed its normal shape. If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.
- Keep the lens wet in the solution recommended by your eye care practitioner.
- Never place a lens on the eye unless it has been fully hydrated (wet) with the recommended rinsing or storing solution. (Refer to the Lens Care Products Chart for the solutions available from Bausch + Lomb.)

### 3. PLACING THE LENS ON THE EYE

There are several methods of lens placement. If the following methods are difficult for you, your eye care practitioner will provide you with an alternate method.

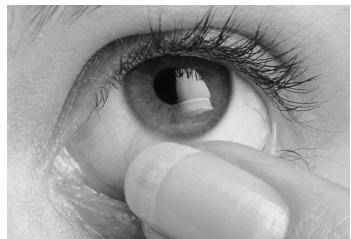
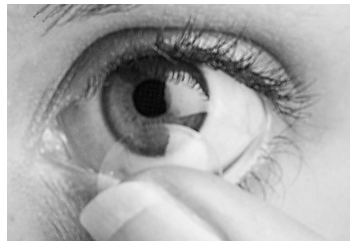
**Note:** *If after placement of the lens, your vision is blurred, check for the following:*

- The lens is not centered on the eye (see “Centering the Lens”, next in this booklet).
- If the lens is centered, remove the lens (see “Removing the Lens” section) and check for the following:
  - a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
  - b. The lens is on the wrong eye.
  - c. The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

#### The One Hand Placement Technique

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





## The Two Hand Placement Technique

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



### If the Lens Feels Uncomfortable, then:

Look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then by blinking, the lens will recenter itself. If the lens still feels uncomfortable, follow the steps described in the section of this booklet entitled "Adverse Reactions".

## 4. CENTERING THE LENS

Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow one of the procedures below.

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.
- or
- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye towards the lens to place it on the center of the eye.

## 5. REMOVING THE LENS

Always remove the same lens first.

- a. Wash, rinse, and dry your hands thoroughly.
- b. Always be sure that the lens is in the correct position on your eye before you try to remove it (a simple check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.

- c. Remove the other lens by following the same procedure.
- d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/ LUBRICATING).

*Note: If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.*

## LENS WEARING SCHEDULES

Your eye care practitioner may either recommend using Bausch & Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lens as a disposable lens or a frequent/planned replacement lens.

**Regardless of the schedule prescribed for you, once a lens is removed at the end of the prescribed wearing period, your eye should have a rest period as recommended by your eye care practitioner.**

### 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 professional'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. PureVision® 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.



# CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING / LUBRICATING)

For continued safe and comfortable wearing of your lenses, it is important that you follow the lens care regimen recommended by your eye care practitioner. Failure to follow the lens care regimen may result in development of serious ocular complications as discussed in the WARNINGS section. **Cleaning and rinsing** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. **Disinfecting** is necessary to destroy harmful germs.

If you require only vision correction, but will not or cannot adhere to a recommended lens care regimen, are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure to practice putting on your lenses and removing them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of these Patient Instructions for Bausch & Lomb PureVision® (balafilcon A) Visibility Tinted Contact Lenses.

## LENS CARE

### 1. 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.

### 2. 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.

### 3. LENS CASE CARE

#### **Instruction for Use:**

Clean contact lens cases with digital rubbing with 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 a fresh, clean tissue is recommended. Air-drying or recapping the lens case lids after use without any additional cleaning methods should be avoided. 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.

### 4. 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 submerged in water when swimming in pools, lakes or oceans, discard them and replace them with a new pair. Ask your eye care practitioner for recommendations about wearing lenses during any activity involving water.

### 5. 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.

### 6. BASIC INSTRUCTIONS

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use **fresh unexpired** lens care solutions.
- Use the recommended chemical (not heat) lens care system and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Lenses prescribed in a frequent replacement program should be thrown away after the expiration of the wearing period prescribed by your eye care practitioner.

- Never rinse your lenses in water from the tap. There are two reasons for this:
  - a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  - b. You might lose the lens down the drain.
- **Clean** one lens first (always the same lens first to avoid mix-ups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning, and rinsing, **disinfect** lenses using the system recommended by your eye care practitioner. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- Your eye care practitioner may recommend a lubricating/rewetting solution for your use. **Lubricating/Rewetting** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

## 7. CHEMICAL (NOT HEAT) DISINFECTION

- Clean the contact lenses with the cleaning solution recommended by your eye care practitioner and thoroughly rinse them with the recommended rinsing solution.
- **After cleaning**, and rinsing, to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by your eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized before wearing. Use ONLY the lens case provided with the hydrogen peroxide care system. This case is specially designed to neutralize the solution.** Failure to use the specialized case will result in severe stinging, burning, and injury to the eye. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the closed storage case until ready to put on your eyes.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to your eyes. A thorough rinse in fresh sterile saline solution prior to placement on your eye should reduce the potential for irritation.

## 8. LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

## 9. CARE FOR A STICKING (NON-MOVING) LENS

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution recommended by your eye care practitioner into your eye. Do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or drops, contact your eye care practitioner immediately. Do not attempt to remove the lens except on the advice of your eye care practitioner.

## 10. CARE FOR A DRIED OUT (DEHYDRATED) LENS

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply the recommended rinsing solution before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour until it returns to a soft state.
- Clean the lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft or if the surface remains dry, **DO NOT USE THE LENS UNTIL IT HAS BEEN EXAMINED BY YOUR EYE CARE PRACTITIONER.**

## 11. 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.**

**NOTE: Therapeutic Wear Emergencies:** For complete information concerning emergency lens care contact your eye care practitioner.

# LENS CARE PRODUCT CHART

The following solutions are available from Bausch + Lomb for use with all Bausch + Lomb Contact Lenses; however, eye care practitioners may recommend alternative products and procedures which should be followed by the patient. Bausch + Lomb® Care Kits are available for lens disinfection, cleaning and storage.

## CHEMICAL LENS CARE SYSTEMS

ACTION	CARE PRODUCT
<b>Cleaning</b>	<i>Bausch + Lomb renu® fresh multi-purpose solution</i> <i>Bausch + Lomb renu® sensitive multi-purpose solution</i> <i>Bausch + Lomb Sensitive Eyes® Daily Cleaner</i> <i>Bausch + Lomb Biotrue® multi-purpose solution</i> <i>Bausch + Lomb renu® Advanced Formula multi-purpose solution</i>
<b>Disinfecting &amp; Storing</b>	<i>Bausch + Lomb renu® fresh multi-purpose solution</i> <i>Bausch + Lomb renu® sensitive multi-purpose solution</i> <i>Bausch + Lomb Biotrue® multi-purpose solution</i> <i>Bausch + Lomb renu® Advanced Formula multi-purpose solution</i>
<b>Rinsing</b>	<i>Bausch + Lomb renu® fresh multi-purpose solution</i> <i>Bausch + Lomb renu® sensitive multi-purpose solution</i> <i>Bausch + Lomb Sensitive Eyes® Plus Saline Solution</i> <i>Bausch + Lomb Biotrue® multi-purpose solution</i> <i>Bausch + Lomb renu® Advanced Formula multi-purpose solution</i>
<b>Rewetting</b>	<i>Bausch + Lomb renu® MultiPlus® Lubricating and Rewetting Drops</i> <i>Bausch + Lomb renu® Rewetting Drops</i>

**Note:** Some solutions may perform more than one function in the care regimen, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

# INSTRUCTIONS FOR THE MONOVISION WEARER

- You should be aware that as with any type of lens correction, there are advantages and disadvantages to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks.
- Some patients have experienced difficulty adapting to monovision contact lens therapy. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation.
- You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state driver's license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.
- If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this option with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.**

# SYMBOL REFERENCE GUIDE

For label and cartons:

The following symbol is for the CE Quality Certification



Meets EU Packaging Directive



Sterilized using steam



Caution



Temperature limit



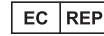
Diameter



Use-by date



Batch code



Authorized representative in the European Community



Prescription only (USA)



Power



Base curve



Effective date



Manufacturer

# PERSONAL WEARING SCHEDULE RECORD

Your eye care practitioner will prescribe your own individual lens wearing schedule and lens replacement schedule. Use the space below to record your schedule and wearing record.

DAY	DATE	HOURS TO BE WORN	HOURS WORN
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
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24			

## CHECK-UP VISITS

Regular check-up examinations by your eye care practitioner are an important part of wearing contact lenses. It is recommended that you follow your eye care practitioner's directions for follow-up examinations. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care practitioner to refer you to a contact lens professional in your new location. Use the space below to record your appointments.

## VISIT SCHEDULE

1.	_____	_____
	Date	Time
2.	_____	_____
	Date	Time
3.	_____	_____
	Date	Time
4.	_____	_____
	Date	Time
5.	_____	_____
	Date	Time
6.	_____	_____
	Date	Time
7.	_____	_____
	Date	Time
8.	_____	_____
	Date	Time
9.	_____	_____
	Date	Time
10.	_____	_____
	Date	Time

## EYE CARE PRACTITIONER INFORMATION

(Please fill out for ready use)

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

Other Information: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Important:** In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given to you, **DO NOT WAIT** for your next appointment. **CONTACT YOUR EYE CARE PRACTITIONER IMMEDIATELY.**

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

# GLOSSARY OF MEDICAL TERMS

<b>Ametropia</b>	Abnormal vision requiring correction for proper focus
<b>Myopia</b>	Nearsighted
<b>Hyperopia</b>	Farsighted
<b>Aphakic</b>	Lacking a crystalline lens (focusing lens inside the eye)
<b>Non-aphakic</b>	Not lacking a crystalline lens
<b>Acute inflammation</b>	Sudden swelling, redness and pain
<b>Subacute inflammation</b>	Gradual swelling, redness and pain
<b>Anterior chamber</b>	Internal portion of the eye, between the cornea and iris
<b>Cornea</b>	Clear, front covering of the eye
<b>Conjunctiva</b>	Membrane that lines the eyelids and the white part of the eye
<b>Corneal ulcer</b>	A sore or lesion on the cornea, which left untreated could lead to permanent loss of vision
<b>Microbial keratitis</b>	An infected corneal ulcer
<b>Hypoxia</b>	Lack of oxygen
<b>Epithelial</b>	Layer of cells on the surface of the cornea
<b>Epithelial microcysts</b>	A small abnormal structure (cyst) in the front surface of the eye
<b>Endothelial polymegathism</b>	Irregular cell size and shape
<b>Neovascularization</b>	Small blood vessels growing into the cornea
<b>Iritis</b>	Internal inflammation of the colored part of the eye (iris)



