Some patients feel that automobile driving performance may not be optimal during the initial wearing period. To help in the adaptation process the patient can be advised to first use the lenses in a visually demanding situation and then to avoid driving during the first several weeks of adaptation. By the time the patient is able to drive under other conditions with caution, treatment success is usually indicated.

If the lens does not begin to move upon blinking after several applications of rewetting solution, the patient should be instructed to use plain water, or if the lens continues to stick, to use a lubricating or rewetting solution. The patient should be instructed to follow the instructions and warnings for lens care handling. The eye care professional should recommend an appropriate lens care regime for the individual patient.

HOW SUPPLIED

Each sterile lens is supplied in a plastic package containing borate buffered saline with a preservative. The lens is sized to fit the patient’s needs.

In the Continental U.S., Alaska, Hawaii
1-800-828-9030

In New York State
1-800-462-1720

In Canada
1-8077100

* All patients should be supplied with a copy of the Bausch & Lomb SofLens daily disposable Contact Lens Patient Information Booklet.

† The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient’s needs.

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For label and cartons:

** Fee Paid for Waste Management

†† Quality System Certification Symbol

SYMBOL REFERENCE GUIDE

CAUTION:

Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.
The Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens is a 3.\(\times\) monomaterial lens in which the lenses are made from the same material throughout. The lens is a spherical lens with a total diameter of 14.0\,mm. The central optic zone diameter is 7.1\,mm, and the lens is produced in a total thickness of 0.032\,mm. All of the lenses are the same thickness providing optimal stability and posterior optic zone diameters are increased thickness from apex to base providing optimal stability and comfort. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D. The lens parameters available in the lens material are not limited to the parameters shown in the table. Oxygen Permeability: 22 x 10–11\,[\text{cm3O2(STP) x cm}/(sec x cm2 x mmHg) @ 35° C Specific Gravity: 1.119
The Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens is a lens designed to correct astigmatism. It is made from a material that allows for oxygen permeability, reducing the risk of eye irritation. The lens is disposable and non-reusable, ensuring hygiene and comfort for the user. It is also designed to adapt to the eye's natural movements, maintaining stability and comfort throughout the day.

**Measurement of Power:**

- **Spherical Power:** The spherical power is determined through traditional methods, such as refraction and keratometry.
- **Cylindrical Power:** The cylindrical power is determined through the use of a diagnostic toric lens. If the diagnostic lens does not provide the desired correction, the power can be increased to achieve the required correction. Conversely, if the lens is too steep, the power should be decreased to avoid discomfort.

**SELECTION OF PATIENTS:**

- **Initial Evaluation:** A thorough eye examination should be conducted, including a check for corneal hypoesthesia (reduced corneal sensitivity) and any signs of infection or irritation.
- **Contact Lens Power:** The contact lens power is ordered based on the patient's prescription and the diagnostic evaluation. For example, if the spectacle prescription is -5.00 -1.75 X 180, the contact lens power would be ordered as -2.25 -0.75 X 180. This power should be increased by 0.25 diopters to compensate for any potential power loss in the lens itself.

**CONTRAINDICATIONS:**

- **Corneal Hypoesthesia:** Patients with a history of corneal hypoesthesia should be advised to wear the contact lens with a lower power or to consider alternative options.
- **Glaucoma:** Contact lenses should not be worn by patients with glaucoma as they may cause an increase in intraocular pressure.
- **Surgery:** Patients who have undergone LASIK or other corneal surgeries should be advised to wait until the surgery area is fully healed before wearing contact lenses.

**PRECAUTIONS:**

- **Washing Hands:** Before handling the contact lenses, hands should be washed with soap and water.
- **Avoiding Foreign Materials:** Contact lenses should be handled carefully to avoid contamination with foreign materials.
- **Water Activity:** Avoid swimming or participating in activities that may cause water to enter the eyes while wearing contact lenses.

**POST-INSERTION:**

- **Discomfort:** If the patient experiences discomfort, the contact lens should be removed and the symptoms should be evaluated by an eye care professional.
- **Eye Examination:** Regular follow-up exams are recommended to monitor the patient's eye health and the effectiveness of the contact lenses.

**ADDITIONAL INFORMATION:**

- **Spherical Power:** The Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens is indicated for patients who require correction of astigmatism. The lens is designed to provide clear vision and can be worn for up to 12 hours per day.
- **Occupational and Environmental Demands:** The lens is suitable for patients with occupational demands that require critical vision, such as pilots or drivers.

**SUMMARY:**

The Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens is a convenient and comfortable option for patients with astigmatism. It is designed to provide clear vision and can be worn for up to 12 hours per day. Proper care and follow-up exams are essential to maintain the health of the patient's eyes and ensure the effectiveness of the contact lenses.
The Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens is a daily disposable, toric contact lens designed to correct astigmatism and provide excellent visibility throughout the day. The lens has a unique Lo-Torque™ design, which results in excellent stability and visual acuity, making it comfortable for use throughout the day.

### PHYSICAL/OPTICAL PROPERTIES

- **Diameter:** 14.2mm
- **Base Curve:** 8.7mm
- **Central Thickness:** 0.08mm
- **Peripheral Thickness:** 0.03mm
- **Optic Zone Diameter:** 6.0mm

### LENS PARAMETERS AVAILABLE

- **Spherical Power Range:** -6.50D to -9.00D in 0.50D steps
- **Cylindrical Power:** -1.25D to -5.00D in 0.25D steps
- **Prism Ballast:** 0.00D to 2.00D in 0.25D steps

### How the Lens Works (Actions)

When placed on the cornea, the Bausch & Lomb SofLens daily disposable Tinted Contact Lens has a unique Lo-Torque™ design that results in excellent stability, visual acuity, and comfort. The lens is easily adaptable to the patient’s corneal shape and provides a nearly constant optical quality, particularly with the blink.

### Patient Selection

A detailed history is crucial to determining patient needs and expectations. Your patient should have a thorough diagnostic examination and a referral to a contact lens specialist. It is important to perform a pre-fitting examination to determine whether a patient is a suitable candidate for daily wear contact lenses. The following steps should be followed:

1. **A prefitting examination should include spherocylinder refraction and VA, keratometry, and biomicroscopic examination.**
2. **Collect and record baseline clinical information to which post-fitting examination results can be compared.**
3. **Determine whether a patient is a suitable candidate for daily wear contact lenses.**
4. **Assess the patient’s visual demands.**
5. **Determine ocular preference.**
6. **Evaluate the patient’s lifestyle.**
7. **Assess the patient’s adherence to the proper, initial daily wearing schedule.**

### Reporting of Adverse Reactions

Due to the small number of patients enrolled in clinical investigations of lenses, all refractive products should carry the following statement:

> Who Should Know That the Patient is Wearing Contact Lenses:

- **Family members**
- **Employers**
- **Friends**
- **Teammates**
- **Co-workers**
- **Roommates**
- **Children**
- **Pet owners**
- **Spouses**
- **Husbands**
- **Wives**
- **Partners**
- **Significant others**

### Wearing Schedule

The wearing schedule for daily disposable contact lenses is typically a 24-hour wear, followed by immediate removal and discard. However, the adaptation period varies for each individual; generally within one week, these symptoms will subside.

- **Dry eyes** may be experienced initially. It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, and eye strain. If these symptoms persist, the patient should consult their eye care professional.
- **Fluorescein**, a yellow dye, should not be used while the lenses are on the eyes. The lenses should be removed and cleaned before the dye is administered. Fluorescein is not recommended for use with monovision contact lenses.

### PRECAUTIONS

- **Due to the small number of patients enrolled in clinical investigations of lenses, all refractive products should carry the following statement:**
  - Due to the small number of patients enrolled in clinical investigations of lenses, all refractive products should carry the following statement:
  - **Any active corneal infection (bacterial, fungal, or viral)**
  - **Acute and subacute inflammation or infection of the anterior chamber of the eye**
  - **Any history of corneal transplant or corneal scar**
  - **Corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations**
  - **Any history of keratitis**
  - **Any history of herpes simplex keratitis**

### Ocular Preference Determination Methods

#### A. Ocular Preference Determination Methods

1. **Ocular Preference Determination Methods**
   - **B. Prior to a follow-up examination, the contact lenses should be worn for at least 4 hours.**
   - **C. The patient should wear the contact lenses for at least 4 hours.**
   - **D. The patient should wear the contact lenses for at least 4 hours.**

### Patient Education

Patient education is crucial to the success of daily wear contact lenses. Eye problems, including corneal ulcers, can develop rapidly and lead to serious injury. Eye care professionals should carefully instruct patients about the following safety measures:

- **Always handle lenses carefully and avoid dropping them.**
- **Be certain that the fingers or hands are free of foreign materials before touching lenses, as small particles can cause scratches or irritations.**
- **Never handle lenses with wet hands, as this can introduce bacteria to the lenses.**
- **Use only the recommended lens care products.**
- **Avoid swimming in contact lenses.**
- **Follow all handling, storage, and cleaning instructions.**
- **Never reuse lens storage solutions.**
- **Never put lenses on overnight or more than 24 hours.**

### Treating Common Conditions

- **Dry eyes** can be managed with over-the-counter artificial tears and lubrication drops.
- **Blue-light sensitivities** can be addressed with the use of blue-light filtering lenses.
- **Eye infections** should be treated with an appropriate course of treatment as directed by an eye care professional.

### Conclusion

The Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens is designed to provide excellent comfort, visual acuity, and stability for patients with astigmatism. Proper selection, fitting, and patient education are essential to the successful use of these lenses. Regular follow-up examinations and adherence to a proper wearing schedule are critical to maintaining excellent visual acuity and comfort throughout the day.
Some patients feel that automobile driving performance may not be optimal during the initial wearing period. Visually demanding situations should be avoided during this time. A patient should be informed that 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 attempted.

Immediately after the correct power lenses are in place, walk across the room and have the patient observe the reactions. Only after these vision tasks are completed should the patient assess the reaction. As the patient continues to look around the room at both near and distance objects, observe the reaction to this mode of correction.

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

- Make use of proper illumination when carrying out visual tasks.
- Having supplemental spectacles to wear over the monovision contact lenses for specific tasks.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- All patients should be supplied with a copy of the Bausch & Lomb SofLens daily disposable lens care guide. The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional.

Other Suggestions

- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Reverse the distance and near eyes if a patient is having trouble adapting.
- Having supplemental spectacles to wear over the monovision contact lenses for specific tasks.

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

- The patient should be instructed to contact the eye care professional or visit a hospital emergency room if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes.
- 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 use plain water, or appropriate and adequate procedures for each individual patient in accordance with the particular lens wearing schedule.
- When lenses are dispensed, the patient should be provided with appropriate and adequate sterile using steam or dry heat, and expiration date.

Report of Adverse Reactions

- The patient should be instructed to report any adverse reactions to:
- Fee paid for waste management
- Sterile using steam or dry heat
- Quality System Certification Symbol
- Cylinder Axis (Degrees)
- Cylinder Power (Diopters)
Some patients feel that automobile driving performance may not be optimal during the adaptation process. The patient can be advised to first use the lenses in a comfortable familiar environment such as in the home. 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.

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. After the patient's performance under the above conditions are completed, tests of visual functions.

1. **Trial Lens Fitting**
   - **Near Add Determination**
   - **1.25 Near Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**

2. **Near Add Determination**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**

3. **Near Add Determination**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**

4. **Near Add Determination**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**

5. **Near Add Determination**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**

6. **Near Add Determination**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**

7. **Near Add Determination**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**
   - **Correct Distance Add**

**Other Suggestions**

- **All patients should be supplied with a copy of the Bausch & Lomb SofLens daily disposable Toric (hilafilcon B) Visibility Tinted Contact Lens Patient Information Booklet.**
- **Care for a Sticking (Nonmoving) Lens**
- **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 ANYTHING OTHER THAN THE RECOMMENDED SOLUTIONS.
  - THE PATIENT SHOULD BE INSTRUCTED TO CONTACT THE EYE CARE PROFESSIONAL AFTER CAREFULLY CONSIDERING THE NATURE OF THE CHEMICAL.

**HOW SUPPLIED**

- **Each sterile lens is supplied in a plastic package containing borate buffered saline with poloxamine.**
- **Each container is marked with the manufacturing lot number of the lens, diopter power, and expiration date.**
- **In Canada**
- **In New York State**
- **In the Continental U.S., Alaska, Hawaii**
- **Toll Free Telephone Number**
  - 1-888-459-5000

**REPORTING OF ADVERSE REACTIONS**

- **IF YOU BELIEVE YOU MAY HAVE AN'ADVERSE REACTION TO THIS PRODUCT, YOU SHOULD CONTACT YOUR EYE CARE PROFESSIONAL OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.**
- **WHEN REPORTING AN ADVERSE REACTION, YOU SHOULD PROVIDE YOUR NAME AND ADDRESS, COUNTRY OF RESIDENCE, THE PRODUCT NAME AND THE BATCH CODE, YOUR DATE OF BIRTH, AND THE DATE YOU TOOK THE PRODUCT.**

**STATE/PROVINCIAL LICENSING**

- **The success of the monovision technique may be further improved by having your patient follow the suggestions below.**
- **Applying the corrective lenses to the patient's eyes if the patient is having trouble adapting.**
- **Having supplemental spectacles to wear over the monovision contact lenses for specific critical near viewing.**
- **Having a third contact lens (near power) to use when critical near viewing is needed.**
- **Having a third contact lens (distance power) to use when critical distance viewing is needed.**

**Conservation Measures**

- **Contact the Eye Profeesional to evaluate the patient's visual needs.**
- **Determine which eye is to be corrected for distance and which eye is to be corrected for near.**
- **Lenses are fit according to the directions in the general fitting guidelines.**
- **Provide optimal reading performance, prescribe the least plus (most minus) of the powers.**
- **Provide for presbyopic patients.**
- **Provide for near vision performance.**

**GENERAL Fitting Guidelines**

- **Provide optimal reading performance, prescribe the least plus (most minus) of the powers.**
- **Provide for presbyopic patients.**
- **Provide for near vision performance.**

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**QUALITY SYSTEM CERTIFICATION SYMBOL**

**REPORTING OF ADVERSE REACTIONS**

**HOW SUPPLIED**

**STATE/PROVINCIAL LICENSING**

**OTHER SUGGESTIONS**

**CONSERVATION MEASURES**

**GENERAL FITTING GUIDELINES**

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