**DESCRIPTION**

In its hydrated state, the Bausch & Lomb SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens is prescribed for single-use disposable wear. For future use, the lens is designed to be removed after an examination that includes appropriate medical background. Patients should receive thorough eye examination instructions prepared by their prescribing eye care professional. The lens is designed to assist healthcare professionals in managing eye care by providing a unique tint that enhances vision and visibility, allowing for easy identification of the lens for removal.

**IMPORTANT:**
After a thorough eye examination, including appropriate medical background, patients should be informed of the following:

- **Lens when any of the following conditions exist:**
  -Dry eye
  -Redness of the eyes
  -Abnormal feeling of something in the eye (foreign body, scratched area)

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

- **Dry eye**
- **Redness of the eyes**
- **Abnormal feeling of something in the eye (foreign body, scratched area)**
- **Occasional tearing (watery eyes) and slight redness during the adaptation period.**

**Topics to Discuss with the Patient:**

- **Do not touch the lens with fingernails.**
- **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 rinsed with a saline solution.
- **Eye care professionals should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye problem develops.** If the lens is damaged, do not put the lens back on the eye. Place the lens in the storage case and contact the eye care professional for analysis and culturing.

**Oxygen Permeability:**

Oxygen Permeability: 22 x 10–11 [cm³O₂(STP) / cm² / mmHg] @35˚C

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

**Fitting Procedure**

**A pre-fitting examination is necessary to:**

- **Have a tendency to drop or lag greater than 2.0 mm on upgaze post-blink.**
- **Vary after a blink.** However, if a lens is only marginally steep, the initial subjective and objective examination.
- **Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.**
- **With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A fit are met.**

**Visual Demands Method**

**Method 1— Determine which eye is the "sighting dominant eye." Have the patient point to an object in each eye. If the patient points to the right eye, then the right eye is the sighting dominant eye.**

**Method 2— Determine which eye is the "near dominant eye." Have the patient point at a near object using each eye.**

**Method 3— Determine which eye is the "near dominant eye." Have the patient look at an object in each eye.**

**B. Monovision**

**C. Visual Demands Method**

**For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for monovision.**

**C. Visual Demands Method**

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for monovision. **Patients selected to wear Bausch & Lomb SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens should be monitored for single-use disposable wear.**

**A serious condition such as infectious corneal ulceration must be managed and treated carefully to avoid more serious complications.**

**B. Precaution:**

**Every 6 months thereafter**

**A. Precaution:**

**Every 6 months thereafter**

**B. Precaution:**

**Every 6 months thereafter**

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner.
Powers (Spherical): +20.00D to -20.00D

IMPORTANT:

1. Initial Lens Power Selection

There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, regular checkups, as determined by the eye care professional, are extremely important.

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30. Initial Lens Power Selection

There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, regular checkups, as determined by the eye care professional, are extremely important.
that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

**DESCRIPTION**

Instructions that pertain to the patient's prescribed lens, and the recommended wearing schedule. Please read carefully and keep this information for analysis and culturing.

**IMPORTANT:**

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive power variations should be noted.

**PRECAUTIONS**

- Problems with contact lenses could result in serious injury to the eye. It is essential that a pretreatment examination be performed before the patient attempts to wear contact lenses.

**ACTIONS**

- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids requires the use of eye protection equipment or may require that you do not wear lenses. Eye care professionals should instruct the patient to REMOVE A LENS IMMEDIATELY if an eye irritation develops.

- Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision.

**DO**

- The lenses are prescribed for disposable wear, and are to be disposed of once they are no longer satisfactory for operating an automobile. During the first several weeks of wear (when adaptation reactions are increased when daily wear lenses are worn overnight).

**DON'T**

- Use creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on cosmetics.

**Other Considerations**

- The lenses are prescribed for daily wear, and are to be disposed of once they are no longer satisfactory for operating an automobile. During the first several weeks of wear (when adaptation reactions are increased when daily wear lenses are worn overnight).

**Patient Communication**

- Patient communication is vital because it relates not only to patient selection but also to ensure patient satisfaction during any follow-up examination.

**Initial Evaluation**

- Initial evaluation of the 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.

**Follow-up Care**

- Follow-up care should be scheduled at regular intervals as determined by the eye care professional.

**Near Add Determination**

- There are circumstances where only one contact lens is required. As an example, an emmetropic patient may wear a contact lens for distance and a +1.75 diopter add for near.

**Success in Fitting Monovision**

- Success in fitting monovision can be improved by the following suggestions:
  - 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 some patients who require amblyopia training.
  - Some patients feel that automobile driving performance may not be optimal during the first several weeks of wear when adaptation is occurring.
  - The patient should be instructed to look at you. Assess the patient's reaction to distance vision under these circumstances.
  - Successful fitting requires that the patient look at you. Assess the patient's reaction to distance vision under these circumstances.
  - For a good prognosis the patient should have adequately corrected distance and near visual acuity.
  - There are circumstances where only one contact lens is required. As an example, a patient may wear a contact lens for distance and a +1.75 diopter add for near.

**Reporting of Adverse Reactions**

- In New York State, the patient should be informed that the following problems may occur:
  - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
  - Discontinuing wear of the contact lenses for at least 24 hours and reinserting them should result in improvement in symptoms.
  - Some patients feel that automobile driving performance may not be optimal during the first several weeks of wear when adaptation is occurring.
  - The patient should be instructed to use a lubricating or preservative solution to help maintain the lens in a hydrated state.
  - The patient should be instructed to promptly contact the eye care professional if any of the previously described adaptive symptoms are normal, and that the adaptation process is unlikely to proceed beyond the initial weeks.

**HOW SUPPLIED**

- The lenses are prescribed for disposable wear, and are to be disposed of once they are no longer satisfactory for operating an automobile. During the first several weeks of wear (when adaptation reactions are increased when daily wear lenses are worn overnight).

**REPORTING OF ADVERSE REACTIONS**

- In New York State, the patient should be informed that the following problems may occur:
  - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
  - Discontinuing wear of the contact lenses for at least 24 hours and reinserting them should result in improvement in symptoms.
  - The patient should be instructed to promptly contact the eye care professional if any of the previously described adaptive symptoms are normal, and that the adaptation process is unlikely to proceed beyond the initial weeks.

**PRODUCT INFORMATION**

- The lenses are prescribed for disposable wear, and are to be disposed of once they are no longer satisfactory for operating an automobile. During the first several weeks of wear (when adaptation reactions are increased when daily wear lenses are worn overnight).

**SPECIAL INSTRUCTIONS**

- Patient Communication is vital because it relates not only to patient selection but also to ensure patient satisfaction during any follow-up examination.

**DISPOSABLE USE**

- The lenses are prescribed for disposable wear, and are to be disposed of once they are no longer satisfactory for operating an automobile. During the first several weeks of wear (when adaptation reactions are increased when daily wear lenses are worn overnight).

**CONTRAINDICATIONS**

- There are circumstances where only one contact lens is required. As an example, a patient may wear a contact lens for distance and a +1.75 diopter add for near.

**PRECAUTIONS**

- Patient Communication is vital because it relates not only to patient selection but also to ensure patient satisfaction during any follow-up examination.

**ADDITIONAL INFORMATION**

- Patient Communication is vital because it relates not only to patient selection but also to ensure patient satisfaction during any follow-up examination.

**REPORTING OF ADVERSE REACTIONS**

- In New York State, the patient should be informed that the following problems may occur:
  - Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.
  - Discontinuing wear of the contact lenses for at least 24 hours and reinserting them should result in improvement in symptoms.
  - The patient should be instructed to promptly contact the eye care professional if any of the previously described adaptive symptoms are normal, and that the adaptation process is unlikely to proceed beyond the initial weeks.

**HANDLING OF LENSES**

- The lenses are prescribed for disposable wear, and are to be disposed of once they are no longer satisfactory for operating an automobile. During the first several weeks of wear (when adaptation reactions are increased when daily wear lenses are worn overnight).

**Sterility**

- Sterile using steam or dry heat.
The lens is to be prescribed for single-use disposable wear, and is to be discarded after each use. It has a diopter range of +20.00D to -20.00D. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The Bausch & Lomb SofLens daily disposable (hilafilcon B) Visibility Tinted Contact Lens is to be prescribed for single-use disposable wear. This package insert is intended for the eye care professional, but should be made available to the patient.

**IMPORTANT:**

- Patients who wear aspheric contact lenses, such as the Bausch & Lomb SofLens daily disposable, should be advised of the following warnings pertaining to contact lens wear:
- The potential impact of these factors on the patient's ocular health should be carefully considered.

**Special Precautions for Eye Care Professionals:**

- Patients should always inform their employer of being a contact lens wearer. Some jobs may weigh the advantages and disadvantages of contact lens wear.
- Patients should inform their doctor (health care professional) about being a contact lens wearer.
- This package insert provides information on the use of contact lenses and suggests that patients be provided with a copy of the SofLens daily disposable package insert.

**FITTING PROCEDURE**

Initial evaluation of the lens should be preceded by a complete eye examination, including but not limited to:
- A general health examination
- A medical history
- An eye examination
- A trial fitting
- A trial lens selection
- An examination of the cornea

The patient should be instructed as to a recommended follow-up schedule. This may include:
- A comprehensive eye examination
- An examination of the cornea
- An examination of the lens

**DIOPTRIC RATING SYSTEM**

Diopter (lens power)

<table>
<thead>
<tr>
<th>Diopter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>+20.00</td>
<td>Strong positive correction</td>
</tr>
<tr>
<td>-20.00</td>
<td>Strong negative correction</td>
</tr>
</tbody>
</table>

**RECOMMENDED REPLACEMENT SCHEDULE**

- 10 days
- 3 months

**HANDLING OF LENSES**

Diopter (lens power)

- 1.4036
- 1.119

**SIGHT-THREATENING OCULAR COMPLICATIONS**

- Redness of the eyes
- Sensitivity to light
- Cells and flare
- Corneal infiltrates

**FITTING CONSIDERATIONS**

- Aphakic patients should not be fitted with SofLens daily disposable Contact Lenses until the patient's eyes have settled.
- Patients who wear aspheric contact lenses should be advised of the potential impact of these factors on the patient's ocular health.
- The patient's eyes should be examined for redness, sensitivity to light, cells, and flare.
- Lenses worn for longer than 10 days or more than one diopter should not be worn.
- Patients should be advised of the potential impact of contact lens wear on their ocular health.

**QUALITY SYSTEM CERTIFICATION**

- The SofLens daily disposable Contact Lenses is certified by the International Organization for Standardization (ISO) 9001:2008 Quality System Certification symbol.

**FREQUENT/PREPLANNED REPLACEMENT SCHEDULE**

- After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and allow the patient to look at the light source for 30 seconds. If the patient has no complaints, the lens is comfortable and provides satisfactory visual performance, it is a well-fitted lens and can be worn again.
- If the patient has complaints, the eye care professional should consider all characteristics of the lens that may be contributing to the patient's symptoms. The patient should be advised of the potential impact of these factors on the patient's ocular health.
- The patient should be instructed as to a recommended follow-up schedule. This may include:
  - A comprehensive eye examination
  - An examination of the cornea
  - An examination of the lens
  - A trial fitting

**MONOVISION**

- 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 diopter) in one eye may not be a good candidate for monovision with the Bausch & Lomb SofLens daily disposable Contact Lenses.
- Example:
  - A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 to 2.00 diopter add.
  - A bilateral myope may require only a distance lens.
  - A bilateral hyperope may require only a near lens.
  - A patient with both a presbyopic and a myopic component may require a +3.00 diopter add to 3.50 diopter add.

**SPECIAL FITTING CONSIDERATIONS**

**A.ocular Preference Determination Methods**

- Method 1— Determine which eye will accept the added power with the least reduction in vision.
- Method 2— Determine which eye will accept the added power with the least reduction in vision.

**B. Refractive Error Method**

- Method 1— Determine which eye will accept the added power with the least reduction in vision.
- Method 2— Determine which eye will accept the added power with the least reduction in vision.

**C. Clinical Judgment Method**

- Method 1— Determine which eye will accept the added power with the least reduction in vision.
- Method 2— Determine which eye will accept the added power with the least reduction in vision.

**D. Visual Demand Situations**

- Visually demanding situations should be avoided during the initial wearing period. A patient should be instructed to first use the lenses in a quiet environment and then graduate to newsprint and finally smaller type sizes.
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**E. Patient Cooperation**

- To help in the adaptation process, the patient can be advised to first use the lenses in a quiet environment and then graduate to newsprint and finally smaller type sizes.
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**F. Patient Follow-up**

- After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and allow the patient to look at the light source for 30 seconds. If the patient has no complaints, the lens is comfortable and provides satisfactory visual performance, it is a well-fitted lens and can be worn again.
- If the patient has complaints, the eye care professional should consider all characteristics of the lens that may be contributing to the patient's symptoms. The patient should be advised of the potential impact of these factors on the patient's ocular health.
- The patient should be instructed as to a recommended follow-up schedule. This may include:
  - A comprehensive eye examination
  - An examination of the cornea
  - An examination of the lens
  - A trial fitting

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- The patient should be instructed as to a recommended follow-up schedule. This may include:
  - A comprehensive eye examination
  - An examination of the cornea
  - An examination of the lens
  - A trial fitting

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- The patient should be instructed as to a recommended follow-up schedule. This may include:
  - A comprehensive eye examination
  - An examination of the cornea
  - An examination of the lens
  - A trial fitting