PRODUCT DESCRIPTION
AIR OPTIX® COLORS (lotrafilcon B) soft contact lenses are made of a lens material that is approximately 33% water and 67% lotrafilcon B, a fluoro-silicone containing hydrogel which is surface treated. A cosmetic pattern is etched on the back surface of the lens, containing a combination of the following color additives: iron oxides, titanium dioxide, [hydrated]borosilicate D; and copper, and phosphotungstic green.

LENS PROPERTIES
• Refractive Index (Hydrated): 1.42
• Light Transmittance: 95% (380 – 780 nm)
• Oxygen Permeability (Dk): 110 x 10^-10 cm³/sec.mm.Hg.
• Base Curve Range: 8.0 to 9.2 mm
• Spherical Power Range: -20.00 to +20.00D
• Chord Diameter: 14.2 mm
• Water Content: 33% by weight in normal saline
• Base Curve Range: 8.0 to 9.2 mm

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.

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AIR OPTIX COLORS (lotrafilcon B) spherical soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and with up to approximately 1.50 diopters of astigmatism that do not interfere with visual acuity.

AIR OPTIX COLORS (lotrafilcon B) lenses with or without refractive power act to enhance or alter the apparent color of the eye.

These lenses may be prescribed for temporary, unplanned replacement wear with daily removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

CONTRAINDICATIONS (REASONS NOT TO USE)
- Do not use AIR OPTIX COLORS (lotrafilcon B) soft contact lenses when any of the following exists:
  - Inflammation or infection of the anterior chamber of the eye
  - Active disease, injury or abnormality affecting the cornea, conjunctiva, or eyelids
  - History of inquisitive eye infection
  - Insufficiency of lacrimal secretions (dry eye) that interferes with contact lens wear
  - Corneal hypothemia (reduced corneal sensitivity)
  - Use of any medication that is contraindicated or interferes with contact lens wear
  - Any systemic disease which may be exacerbated by or interferes with contact lens wear
  - Allergic reactions or ocular irritation of the ocular surfaces or adnexa that may be caused by or exacerbated by the wearing of contact lenses
  - Alkali injury or exposure to a chemical that may be used to care for the contact lenses
  - Patient history of recurring eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or allergic reaction to contact lenses
  - If eyes become red or irritated

WARNINGs
- Advise patients of the following warnings pertaining to contact lens wear:
  - Problems with contact lenses (with or without corrective power) and lens care products could result in serious injury to the eye. It is essential that patients follow the eye care professional's directions 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 permanent eye damage.
  - Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results* have shown that the risk of ulcerative keratitis is greater, for daily wearers who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight.
  - Studies have shown that contact lens wearers who smoke have a greater risk of suffering ulcerative keratitis than among those who are non-smokers.
  - If a patient experiences eye discomfort, foreign body sensation, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to stop wearing the lenses and promptly contact his or her eye care professional. It is recommended that contact lens wearers see their eye care professional regularly as directed.

PRECAUTIONS
- To prevent damage to the eyes or to the contact lenses, the following precautions should be taken:
  - Special Precautions for the Eye Care Professional: Due to the small number of patients enrolled in the clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently when selecting an appropriate lens design and parameters, the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, central and peripheral ulcerative keratitis, and lens and contact lens related complications. The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore the continuing ocular health of the patient and lens performance on the eye should be carefully evaluated on initial dispensing and monitored on an ongoing basis by the prescribing eye care professional.
  - The following patients may not be suitable candidates and/or may experience a higher rate of adverse effects associated with contact lens wear:
    - Patients with a history of non-compliance with contact lens care and disinfection regimes, wearing restrictions, scheduling follow-up visits or who are not carefully evaluated on initial dispensing and monitored on a continuing basis by the prescribing eye care professional.

- Lenses should be disposed of and replaced according to the eye care professional's recommendations.
  - Note the correct lens power for each eye to prevent getting them mixed up.
  - Always keep a supply of replacement lenses on hand.
  - Do not use lenses beyond their expiration date.

- Solution Precautions:
  - Eye injury due to irritation or infection may result from lens contamination. To determine the risk of contamination, review the appropriate manufacturer's labeled lens care instructions with the patient (see LENS CARE DIRECTIONS).
  - Only use fresh, unexpired lens care solutions recommended for use with soft contact lenses and follow directions in the product package insert.
  - If a lens is exposed to air while off the eye it may become dry, brittle, and permanently damaged. If this should occur, the lens should be discarded and replaced with a new one to avoid possible irritation or injury to the eye. Always keep the lenses completely immersed in the recommended storage solution when lenses are not being used.

- Lenses: Do not use AIR OPTIX COLORS (lotrafilcon B) contact lenses for contact lens or saline care products.
  - Saliva or anything other than the recommended solution for lubricating or wetting lenses should not be used with the lenses.

Lens Case Precautions:
- Lenses can be a source of bacterial growth and require proper use, cleaning and replacement at regular intervals as recommended by the lens case manufacturer or eye care professional.

Other Topics to Discuss with Patients:
- Periodic眼前 examinations are especially important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine corneal response. Alcon recommends that patients see their eye care professional once each year as recommended by the eye care professional.
- Certain medications may cause dryness of the eye, increased lens awareness, lens intolerance, and blurred vision or visual changes. These include, but are not limited to, antihistamines, decongestants, corticosteroids, muscle relaxants, tranquilizers, and those for motion sickness. Caution patients using such medications accordingly and prescribe proper remedial measures.
  - Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.
- Patients should be warned not to share their lenses with anyone as this may spread microorganisms which could result in serious eye health problems.

Who Should Know that the Patient is Wearing Contact Lenses:
- Patients should inform their employers that they are wearing contact lenses. Some jobs may require the use of eye protection equipment or may require that contact lenses not be worn.

- It is strongly recommended that patients be provided with a copy of the Patient Instruction Booklet for AIR OPTIX® COLORS (lotrafilcon B) contact lenses, available from Alcon, and understand its contents prior to dispensing the lenses.

ADVERSE REACTIONS
- Patients should be instructed to check eyes regularly to make sure they look well, feel comfortable and vision is clear. Potentially serious complications are usually accompanied by one or more of the following signs or symptoms:
  - Moderate to severe eye pain not relieved by removing the lens
  - Foreign body sensation
  - Excessive watering or other eye symptoms including mucopurulent discharge
  - Redness of the eyes
  - Photophobia (light sensitivity)
  - Blurred, stinging, itching or tearing of the eye
  - Moderate to severe eye pain not relieved by removing the lens
  - The patient should be instructed to NOT use a new lens as self-treatment for the problem.
- The patient should be informed that a serious condition such as corneal ulcer, infection, corneal vascularization, or iritis may be present, and may progress rapidly. Lens care products such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated appropriately.
- Additional contact lens wear may be associated with corrosion that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized infections caused by bacteria, fungi, yeasts, protozoa, and other microorganisms which may lead to chronic eye disease, erosion, or visually significant opacification of the cornea.

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ADVERSE REACTION REPORTING
If a patient experiences any serious adverse effects associated with the use of AIR OPTIX COLORS (lithium ion) contact lenses, please notify Alcon Medical Safety at 1-800-241-5999.

FITTING GUIDE AND PATIENT BOOKLET
Conventional methods of fitting contact lenses apply to AIR OPTIX COLORS (lithium ion) contact lenses. For a detailed description of the fitting techniques, refer to the AIR OPTIX COLORS (lithium ion) Professional Fitting and Information Guide. Both the professional fitting guide and a patient instruction booklet are available free of charge from Alcon Laboratories, Inc.

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099, USA
1-800-241-5999

LENS WEAR & REPLACEMENT SCHEDULES
The wearing and replacement schedule should be determined by the eye care professional.

DAILY WEAR
(less than 24 hours, while awake):
- To avoid tendency of the daily wear patient to overwear the lenses initially, stress the importance of adhering to a proper, initial wearing schedule.

Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear. Patients must adhere to a recommended regimen based upon the patient's individual needs and physiological conditions.

- The maximum wear time should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary. There may be a tendency for patients to overwear the lenses initially. The eye care professional should stress the importance of adhering to the initial maximum wearing schedule.

- The above instructions are typical for a lens cleaning product, however you must always consult the instructions for the specific lens care product.

WATER ACTIVITIES
Do not expose your contact lenses to water while you are 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, you should discard them and replace them with a new pair.

Ask your eye care practitioner (professional) for recommendations about wearing your lenses during any activity involving water.

LENS CARE DIRECTIONS
Patients must adhere to a recommended care regimen. Lenses must be cleaned, rinsed, and disinfected after removal and prior to reinsertion on the eye according to the instructions in the package inserts provided with the lens care products purchased. Failure by the eye care professional to follow the complete regimen in accordance with manufacturer’s instructions in the package inserts may contribute to problems (see ADVERSE REACTIONS) and/or result in the development of serious ocular complications as discussed in WARNINGS.

Basic Instructions for Lens Cleaning and Disinfection:
When lenses are disinfected, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package label presented below. IMPORTANT: Hydrogen peroxide disinfecting solutions, such as CLEAR CARE Cleaning and Disinfecting Solution, are not multi-purpose solutions. For hydrogen peroxide disinfecting solutions follow the manufacturer’s instructions.

- Soaking and Storing Your Lenses
  - Use only fresh lens disinfecting solution each time you soak (store) your lenses.

Warning:
- Do not reuse or “top off” old solution left in your lens case since solution reuse reduces effective lens disinfection and could lead to severe infection, vision loss or blindness.

- Trapping off” is the addition of fresh solution to solution that has been sitting in your case.

- Rub and Rinse Times
  - Rub and rinse your lenses according to the lens care manufacturer’s instructions. Typical instructions would be: “Rub and rinse your lenses for [X] seconds or more (e.g., 10 seconds or more) and then repeat with the second for a total of 2 times” (e.g., 10 seconds or more).

Follow the complete recommended lens rubbing and rinsing times in the labeling to adequately disinfect your lenses and reduce the risk of contact lens infection.

Warning:
- Rub and rinse your lenses for the recommended amount of time to help prevent serious eye infections.

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

- Discard Date for Lens Cleaning and Disinfecting Solutions
  - After opening, discard any remaining solution after the period recommended by the lens care manufacturer. If you are using CLEAR CARE Cleaning and Disinfecting Solution discard any remaining solution 6 months after opening.

Warning:
- Using your lens care solution beyond the discard date could result in contamination of the solution and can lead to severe infection, vision loss or blindness.

- The above instructions are typical for a lens cleaning product, however you must always consult the instructions for the specific lens care product.

Alcon recommends a chemical (not heat) method of disinfection such as CLEAR CARE Cleaning and Disinfecting Solution or OPTI-FREE PureMoist Multi-Purpose Disinfecting Solution.

- Use of OZONETM+ an enzymatic cleaner, is optional and may be recommended by the eye care professional if warranted.

- Lens compatibility with an abrasive type cleaner such as OPTI-CLEAN® II D is anything other than tested and is not recommended.

- Heat disinfection has not been tested and is not recommended.

Basic Instructions for Lens Case Care:
- The eye care professional should review the instructions for the specific lens care product used by the patient. Typical instructions are:
  - Clean contact lens cases with digital rubbing using fresh, sterile disinfecting solutions/contact lens cleaner. Never use water. Cleaning should be followed by rinsing with fresh, sterile disinfecting solutions (never use water) and wiping the lens cases with fresh, clean tissue is recommended. Air-drying or recapining the lens case lids after use and/or without any additional cleaning methods should be discouraged. Air-drying, be sure that the residual solution remains in the case before allowing it to air dry.

- Replace your lens case at least once every 3 months, or as recommended by the lens case manufacturer. Contact lens cases can be a source of bacterial growth.

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

The above instructions are typical for a lens case, however you must always consult the instructions for the specific lens case.

To help avoid serious eye injury from contamination:
- Always wash, rinse and dry hands before handling the lenses.

- Use only fresh sterile solutions recommended for use with soft (hydrophilic) contact lenses. When opened, sterile non-preserved solutions must be discarded at the time specified in the label directions.

- Do not use saliva, tap water, homemade saline solution, distilled water, or anything other than a recommended sterile solution indicated for the care of soft lenses.

- Do not reuse solutions.

- Use only fresh solutions for each lens care step. Never add fresh solution to old solution in the lens case.

- Follow the manufacturer’s instructions for care of the lens case.

- Replace the lens case at regular intervals to help prevent cross contamination by microorganisms that can cause eye infection.

- Never use a hard (rigid) lens solution unless it is also indicated for use with soft contact lenses. Corneal injury may result if hard (rigid) lens solutions not indicated for use with soft lenses are used in the soft lens care regimens.

- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn to avoid lens dehydration.

- Unless specifically indicated in the labeling, do not alternate, change, or mix lens care systems or solutions for any one pair of lenses. If in doubt as to solution suitability, consult the eye care professional.

CARE FOR A STICKING LENS
If the lens sticks (stops moving) or begins to dry on the eye, instruct the patient to apply several drops of a recommended lubricating solution used in accordance with package labeling. The patient should wait until the lens begins to move freely on the eye before attempting to remove it. If the lens continues to stick, the patient should IMMEDIATELY consult the eye care professional.

IN OFFICE USE OF TRIAL LENSES
Eye care professionals should educate contact lens technicians concerning proper use of trial lenses.

Each contact lens is shipped sterile in a blister pack containing phosphate buffered saline with 0.2% hypophosphates/Dimethylolaminonehydroxyethylpolysiloxane (HP/DMOHES) Copolymer and is steam sterilized STERILE. The package is marked with the base curve, diameter, dioptic power, lens color, manufacturing lot number and expiration date.

The following may appear on labels or cartons:

<table>
<thead>
<tr>
<th>Symbols/Signs</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAUTION</td>
<td>Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.</td>
</tr>
<tr>
<td>Batch code</td>
<td>Use by date or dry date</td>
</tr>
<tr>
<td>Example of two letter language code (English)</td>
<td>DIA</td>
</tr>
<tr>
<td>Base curve</td>
<td>Alcon Laboratories, Inc.</td>
</tr>
<tr>
<td>C Jain</td>
<td>Authorized Representative European Community</td>
</tr>
<tr>
<td>European conformity sign</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>See product instructions</td>
<td>Packaging waste license sign</td>
</tr>
</tbody>
</table>

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1Check for actual product availability which may change over time

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