

**IMPORTANT:** This package insert is effective as of February 2014 and applicable to the AIR OPTIX<sup>®</sup> COLORS (Iotrafalcon B) contact lenses described below. Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses. Copies of this package insert are available without charge from Alcon by calling Customer Service at 1-800-241-5999 or download from our website at www.alcon.com. In addition a *Patient Instruction Booklet* is available which is recommended to be given to patients.



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

**PRODUCT DESCRIPTION**

AIR OPTIX<sup>®</sup> COLORS (Iotrafalcon B) soft contact lenses are made of a lens material that is approximately 33% water and 67% Iotrafalcon B, a fluoro-silicone containing hydrogel which is surface treated. A cosmetic pattern is embedded into the back surface of the lens, containing a combination of the following color additives: iron oxides, titanium dioxide, [phthalocyaninato (2-)] copper, and phthalocyanine green.

**LENS PROPERTIES**

- Refractive Index (hydrated): 1.42
- Light Transmittance: > 95% (380 – 780 nm)
- Oxygen Permeability (Dk):  $110 \times 10^{-11}$  (cm<sup>2</sup>/sec)(ml O<sub>2</sub>/ml x mm Hg), measured at 35°C (intrinsic Dk - Coulometric method)
- Water Content: 33% by weight in normal saline

**LENS PARAMETERS**

- Diameter Range 13.0 to 15.0 mm
- Spherical Power Range -20.00 to +20.00D
- Base Curve Range 8.0 to 9.2 mm

**LENS PARAMETERS AVAILABLE<sup>1</sup>**

**AIR OPTIX COLORS (Iotrafalcon B) spherical**

- Chord Diameter: 14.2 mm
- Center Thickness: 0.08 mm @ -3.00D (varies with power)
- Base Curve: 8.6 mm
- Powers: +6.00D to -6.00D (0.25D steps; incl. plano); -6.50D to -8.00D (0.50D steps)

**ACTIONS**

When hydrated and placed on the cornea, AIR OPTIX COLORS (Iotrafalcon B) soft contact lenses act as a refracting medium to focus light rays on the retina.

**INDICATIONS (Uses)**

**AIR OPTIX COLORS (Iotrafalcon 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 does not interfere with visual acuity.

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

The lenses may be prescribed for frequent/planned 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 (Iotrafalcon 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
- Microbial infection of the eye
- Insufficiency of lacrimal secretion (dry eye) that interferes with contact lens wear
- Corneal hypoesthesia (reduced corneal sensitivity)
- Use of any medication that is contraindicated or interferes with contact lens wear, including eye medications
- 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
- Allergy to an ingredient in a solution which must 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 abnormal ocular response to contact lens wear
- 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 their 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 loss of vision.**
- Daily wear lenses are not indicated for overnight wear, and patients should be instructed not to wear lenses while sleeping. Clinical study results<sup>2</sup> have shown that the risk of ulcerative keratitis is greater for daily wear users who wear their lenses overnight (outside the approved indication) compared to those who do not wear them overnight.
- Studies<sup>2</sup> have shown that contact lens wearers who smoke have a greater risk of suffering ulcerative keratitis than among those who are nonsmokers.
- If a patient experiences eye discomfort, foreign body sensation, excessive

tearing, vision changes, or redness of the eye, the patient should be instructed to immediately remove lenses and promptly contact his or her eye care 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 thickness and optic zone diameter.

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 regimen, wearing restrictions, wearing schedule or follow-up visit schedule.**
- **Patients who are unable or unwilling to understand or comply with any directions, warnings, precautions, or restrictions. Contributing factors may include but are not limited to age, infirmity, other mental or physical conditions, and adverse working or living conditions.**
- Contact lenses, even if worn for cosmetic reasons only, are prescription medical devices and must only be worn under the prescription, direction and supervision of an eye care professional. The eye care professional needs to determine whether these lenses are appropriate for the individual patient and needs to ensure proper fit on the patient's individual eyes.
- Fluorescein, a yellow dye, should not be used while the lenses are on the patient's eyes. The lenses absorb this dye and become discolored. Whenever fluorescein is used, the eyes should be flushed thoroughly with sterile saline solution that is recommended for in eye use prior to inserting lenses. Avoid dispensing saline from an aerosol can directly into the eye.
- Before leaving the eye care professional's office, the patient should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Eye care professionals should make arrangements with the patient for appropriate follow-up visits. Alcon recommends that patients see their eye care professional once each year, or more often, as recommended by the eye care professional.
- Diabetics may have reduced corneal sensitivity and thus are more prone to corneal injury and do not heal as quickly or completely as non-diabetics.
- Visual changes or changes in lens tolerance may occur during pregnancy or use of oral contraceptives. Caution patients accordingly.
- Cosmetically tinted contact lenses may cause reduced visibility in low light conditions.

**Eye Care Professionals should carefully instruct patients about the following care regimen and safety precautions:**

**Handling Precautions:**

- Be sure that before leaving the eye care professional's office the patient is able to promptly remove lenses or have someone else available to remove them.
- Good hygiene habits help promote safe and comfortable lens wear. **Always wash, and rinse hands before handling lenses.**
- **REMOVE A LENS IMMEDIATELY** if an eye becomes red or irritated.
- Carefully follow the handling, insertion, removal, cleaning disinfecting, storing and wearing instruction in the Patient Instruction Booklet for AIR OPTIX<sup>®</sup> COLORS contact lenses.
- Always handle lenses carefully. If a lens is dropped, small particles or fibers may adhere to the lens surface which can irritate the eye. Lenses should be cleaned and disinfected prior to insertion or replaced with a sterile, fresh new lens.
- Never use tools, tweezers or sharp objects such as fingernails to insert or remove lenses from the lens container or eye. Pour the lens into the hand.

**Lens Wearing Precautions:**

- Patients should never exceed the prescribed wearing schedule regardless of how comfortable the lenses feel. Doing so may increase the risk of adverse effects.
- The lens should move freely on the eye at all times. If the lens sticks (stops moving) on the eye, follow the recommended directions in the *Care for a Sticking Lens* section. If non-movement of the lens continues, the patient should be instructed to consult their eye care professional immediately.
- Never allow contact lenses to come into contact with non-sterile liquids (including tap water and saliva) as microbial contamination can occur, which may lead to permanent eye damage.
- Eye irritation, infection, or lens damage may result if cosmetics, lotion,

soap, cream, hair spray, deodorant, aerosol products or foreign particles come in contact with lenses. If sprays are used, eyes should be kept closed until the spray has settled.

- Environmental fumes, smoke, and vapors should be avoided in order to reduce the chance of lens contamination or physical trauma to the cornea.
- 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 reduce 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 inserts.
- 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 worn.
- Do not use thermal (heat) disinfection and do not heat lens 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:**

- Contact lens cases 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 eye examinations are extremely important for contact lens wearers. Schedule and conduct appropriate follow-up examinations to determine ocular response. Alcon recommends that patients see their eye care professional once each year or 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, diuretics, 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<sup>®</sup> COLORS (Iotrafalcon 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 secretions including mucopurulent discharge
- Redness of the eyes
- Photophobia (light sensitivity)
- Burning, stinging or itching or other pain associated with the eyes
- Comfort is less compared to when the lens was first placed on eye
- Poor visual acuity (reduced sharpness of vision)
- Blurred vision, rainbows or halos around objects
- Feeling of dryness

**Patients should be instructed that if any of the above signs or symptoms are noticed, he or she should:**

- **IMMEDIATELY REMOVE THE LENSES.**
- **If the discomfort or problem stops**, then look closely at the lens(es).
  - If the lens(es) is in any way damaged, DO NOT put the lens(es) back on the eye. Discard damaged lens(es), and contact the eye care professional.
  - If the lens(es) have dirt, an eye lash or other foreign body on it, thoroughly clean, rinse, and disinfect prior to reinsertion
- **If the discomfort or problem continues after removing lens(es) or upon reinsertion, IMMEDIATELY remove the lens(es) and contact the eye care professional for identification of the problem and prompt treatment to avoid serious eye damage.**
- The patient should be instructed **NOT** to 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. Less serious reactions such as abrasions, infiltrates, and bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

- Additionally, contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining, infiltrates, neovascularization, endothelial polymegathism, tarsal papillary changes, conjunctival injection or iritis.

#### ADVERSE REACTION REPORTING

If a patient experiences any serious adverse effects associated with the use of AIR OPTIX® COLORS (lotrafilcon B) contact lenses, please notify: Alcon Medical Safety in the USA at 1-800-241-7468.

#### FITTING GUIDE AND PATIENT BOOKLET

Conventional methods of fitting contact lenses apply to AIR OPTIX COLORS (lotrafilcon B) contact lenses. For a detailed description of the fitting techniques, refer to the AIR OPTIX COLORS (lotrafilcon B) *Professional Fitting and Information Guide*. Both the professional fitting guide and a patient instruction booklet are available free of charge from:

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 per 24 hour period.
- It may be advisable for patients who have never worn contact lenses previously to be given a wearing schedule that gradually increases wearing time over a few days. This allows more gradual adaptation of the ocular tissues to contact lens wear.
- The maximum daily wearing 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. Studies have not been conducted to show that AIR OPTIX COLORS (lotrafilcon B) contact lenses are safe to wear during sleep, therefore patients should be advised to remove their lenses while sleeping. Normal daily wear of lenses assumes a minimum of 6 hours of non-lens wear per 24 hour period. Optimum individual wearing schedule will vary.

#### LENS REPLACEMENT

The replacement schedule is determined by the eye care professional based upon the patient's individual needs and physiological conditions. Alcon recommends a replacement schedule of up to four weeks for lotrafilcon B lenses, or as recommended by the eye care professional.

#### 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 recommended by the eye care professional. Failure 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 dispensed, the eye care professional should recommend an appropriate system of lens care and provide the patient with instructions according to the package labeling.

- The eye care professional should review the following instructions with the patient:
- **Lenses must be cleaned, rinsed, and disinfected each time they are removed, for any reason.** If removed while the patient is away from the lens care products, the lenses may not be reinserted, but should be stored until they can be cleaned, rinsed, and disinfected.
- **Cleaning** is necessary to remove mucus, film, and contamination from the lens surface. **Rinsing** removes all traces of the cleaner and loosened debris. **Disinfecting** is necessary to destroy remaining microorganisms.
- Lenses must be cleaned, rinsed, disinfected, and stored in accordance with the package labeling of the lens care products recommended by the eye care professional. Typical instructions for lens care products include the steps 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 contact 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. "Topping-Off" is the addition of fresh solution to solution that has been sitting in your case.

- Rub and Rinse Time
  - 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 side for a total of 2 times "X" seconds (e.g., 20 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 3 months after opening. *If you are using OPTI-FREE® PureMoist® Multi-Purpose 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 UNIZYME® 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 Daily Cleaner has not been 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 case with 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 recapping the lens case lids after use without any additional cleaning methods should be discouraged. If air drying, be sure that no 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 after 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 case 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 regimen.
- 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 solution. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to ensure sterility, the blister pack should not be opened until immediately prior to use. For fitting


and diagnostic purposes, the lenses should be disposed of after a single use and not be re-used from patient to patient.

#### EMERGENCIES













The patient should be informed that if chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should:

**flush eyes immediately with tap water or fresh saline solution, remove the lenses and place them in the recommended storage solution, and call or visit the eye care professional or a hospital emergency room immediately.**

#### HOW SUPPLIED

Each lens is packaged in a foil-sealed plastic container containing isotonic phosphate buffered saline with 0.2% Vinylpyrrolidone/Dimethylaminoethylmethacrylate Copolymer (VP/DMAEMA Copolymer) and is steam sterilized (STERILE ). The package is marked with the base curve, diameter, diopter power, lens color, manufacturing lot number and expiration date.

The following may appear on labels or cartons:

Symbols/Signs	Description
	CAUTION: Federal (United States) law restricts this device to sale by or on the order of a licensed eye care professional.
	Steam sterilized
	Use by date (Expiry date)
	Batch code
	Example of two letter language code (English)
	Diameter
	Base curve
	Lens power
	European conformity sign
	See product instructions
	Authorized Representative European Community
	Manufacturer
	Packaging waste license sign

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<sup>1</sup> Check for actual product availability which may change over time

<sup>2</sup> New England Journal of Medicine, September 21, 1989; 321 (12), pp.773-783.

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