

THIS LEAFLET CONTAINS IMPORTANT PRODUCT USE AND SAFETY INFORMATION. PLEASE READ CAREFULLY AND RETAIN FOR FUTURE REFERENCE. CONTACT LENSES SHOULD ALWAYS BE FITTED BY AN EYE CARE PROFESSIONAL. IT IS ESSENTIAL THAT YOU FOLLOW YOUR EYE CARE PROFESSIONAL'S DIRECTIONS AND ALL LABELING INSTRUCTIONS FOR PROPER USE OF YOUR CONTACT LENSES.

PRODUCT IDENTIFICATION (Name)

AIR OPTIX* COLORS (Iotrafilcon B) soft contact lenses for daily wear

PRODUCT DESCRIPTION

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

Lens Properties:

- Refractive Index (hydrated): 1.42
- Luminous Light Transmittance: 95% ± 5%
- Oxygen Permeability (Dk): 110 x 10⁻¹¹ (cm²/sec) (ml O₂ /ml x mm Hg), measured at 35°C (intrinsic Dk-Coulometric method)
- Water Content: 33% by weight in normal saline

INDICATIONS (Uses)

AIR OPTIX* COLORS (Iotrafilcon B) spherical soft contact lenses with refractive power 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 (Iotrafilcon B) lenses, with or without refractive power, act to enhance or alter the apparent color of the eye.

The lenses are to be used 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. Lenses should be discarded and replaced with a new pair each month, or more often, if recommended by the eye care professional.

CONTRAINDICATIONS (Reasons Not to Use)

Do not use AIR OPTIX* COLORS (Iotrafilcon B) soft contact lenses when any of the following exists:

- Allergy, inflammation, infection or irritation in or around the eye or eyelids
- Inadequate tear film (dry eye)
- 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 safe contact lens wear, handling, and/or care
- If eyes become red or irritated

WARNINGS

- Daily wear lenses are not indicated for overnight wear. AIR OPTIX* COLORS soft contact lenses should not be worn while sleeping.
- Serious eye problems, including corneal ulcers (ulcerative keratitis), can develop rapidly and lead to loss of vision.
- Contact lens wear increases the risk of eye infections. Sleeping in lenses (napping or overnight use) and/or smoking further increases the risk of ulcerative keratitis for contact lens users (Schein, 1989).
- 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.
- Problems with contact lenses and lens care products could result in serious injury to the eye. It is essential to follow the eye care professional's directions and all labeling instructions for proper use of lenses and lens care products.
- Non-sterile liquids (i.e. tap water, distilled water, homemade saline solution, or saliva) should not be used as a substitute for any component in the lens care process. The use of tap and distilled water has been associated with *Acanthamoeba* keratitis, a corneal infection that is resistant to treatment and cure.

General Emergencies:

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes:

- Flush eyes immediately with fresh saline solution or tap water.
- Remove and discard the lens and immediately contact your eye care professional or visit a hospital emergency room without delay.

PRECAUTIONS

Special Precautions for the Eye Care Professional:

- 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.
- Trial lenses for fitting and diagnostic purposes are not intended for multi-patient use.

- The 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.
- 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.
- Cosmetically tinted or printed contact lenses may cause reduced visibility in low light conditions.
- 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.
- Eye care professionals should instruct the patient to remove the lenses immediately if the eye becomes red or irritated.
- Before leaving the eye care professional's office, patients should be able to promptly remove their lenses or should have someone else available who can remove their lenses for them.
- Routine eye examinations are necessary to help assure the continued health of the patient's eyes. Alcon recommends that patients see their eye care professional at least once each year, or more often, as recommended by the eye care professional.

Lens Wearing Precautions:

- Check eyes daily to ensure they look well, feel comfortable and your vision is clear.
- Do not use if blister package is damaged or not sealed completely. This may result in product contamination which can lead to a serious eye infection.
- In the interest of maintaining the health and safety of your eyes, the lens wearing schedule should be determined by an eye care professional. Do not wear AIR OPTIX* COLORS soft contact lenses while sleeping.
- Do not share lenses with anyone as this may spread micro-organisms, which could result in serious eye health problems.
- 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.
- Consult your eye care professional before wearing lenses during sports activities including swimming and water related activities to prevent exposure to microbial contamination or lens damage.
- Remove and discard lenses when exposed to noxious or irritating vapor.
- Discard a contact lens that has become dehydrated or damaged. Replace with a fresh new lens.
- It is recommended that contact lens wearers visit their eye care professional at least once per year, or as directed.
- Inform employer that you wear contact lenses, especially if your job involves using eye protection equipment.
- Keep a note of the correct lens power for each eye. Before lens insertion, check that the lens power on each foil pack is correct for that eye.
- Be careful while using soaps, lotions, creams, cosmetics or deodorants as they can cause irritation if they come into contact with your lenses.
- Insert lenses before applying make-up and remove them before taking make-up off.
- Always carry spare lenses with you or have back-up spectacles available.
- Do not use lenses after the expiry date.
- Cosmetically tinted or printed contact lenses may cause reduced visibility in low light conditions.
- AIR OPTIX* COLORS contact lenses contain iron oxide, a metallic-based colorant. Remove the lenses before undergoing Magnetic Resonance Imaging (also called MRI or MR scan).

ADVERSE EFFECTS (Possible problems and what to do)

Problems may occur with contact lens wear and may first present as one or more of the following signs and symptoms:

- Foreign body sensation (feeling of something in the eye)
- Uncomfortable lens
- Eye redness
- Photophobia (sensitivity to light)
- Burning, stinging, itching or watering eyes
- Reduced sharpness of vision
- Rainbows or halos around lights
- Increased eye secretions
- Discomfort or pain
- Severe or persistent dry eyes

These symptoms, if ignored, may lead to more serious complications.

WHAT TO DO IF A PROBLEM OCCURS

If any of the above signs or symptoms occur:

- Immediately remove the lens(es).
- If the signs or symptoms stop, then look closely at the lens(es).
 - o If the lens is in any way damaged, do not put it back on the eye. Replace with a new lens or consult your eye care professional.
 - o If the lens has dirt, an eyelash, or foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens before reinsertion.
- If the signs or symptoms continue after removal or recur upon reinsertion of the lens, remove the lens immediately, then promptly contact your eye care professional.
- A serious condition such as infection, corneal ulcer (ulcerative keratitis) or iritis may be present.
 - o These conditions could progress rapidly and may lead to permanent loss of vision.
 - o Less serious reactions such as abrasions, epithelial staining and bacterial conjunctivitis must be managed and treated early to avoid complications.
- Occasional dryness may be relieved by blinking fully several times or by the use of contact lens rewetting drops that are approved for use with soft contact lenses. If dryness persists, consult your eye care professional.
- If a lens sticks (stops moving), apply several drops of a contact lens rewetting solution and wait until the lens begins to move freely on the eye before attempting to remove it. If this problem persists, consult your eye care professional.
- If a lens decenters on the eye, it may be possible to recenter it by:
 - o Closing your eyelids and gently massaging the lens into place, or
 - o Looking in the direction of the lens and blinking gently, or

- o Gently pushing the off-centered lens onto the cornea with light finger pressure on the edge of the upper or lower eyelid.
- If a lens tears in your eye, remove the pieces carefully by pinching them as you would for normal lens removal. If the lens pieces do not seem to remove easily, do not pinch the eye tissue. Rinse with saline. If this does not help, contact your eye care professional for assistance.

DIRECTIONS FOR USE (LENS CARE DIRECTIONS)

RECOMMENDED WEAR AND REPLACEMENT SCHEDULE

The wearing and replacement schedule should be determined by an eye care professional based on the patient's individual needs and physiological conditions. The lenses are approved for daily wear only and should be discarded and replaced with a new pair each month, or more often, if recommended by the eye care professional.

LENS HANDLING INSTRUCTIONS

- Always wash and rinse your hands thoroughly and dry completely with a clean, lint free towel before handling contact lenses.
- Gently shake the blister pack (containing a fresh new lens) prior to opening.
- Remove the lens from the blister pack (or lens storage case for previously worn lenses) by carefully pouring it onto the palm of your hand.
- Ensure the lens is right side out and that you have the correct lens for each eye.
- Inspect your lenses prior to insertion.
- Insert lenses only if they appear to be clean and undamaged.

LENS INSERTION INSTRUCTIONS

- Wash and rinse your hands thoroughly and dry completely with a clean, lint free towel before handling contact lenses.
- Place a lens on the tip of your right or left index finger. Place the middle finger of the same hand close to lower eyelashes and pull down the lower eyelid.
- Use the fingers of the other hand to lift the upper eyelid.
- Place the lens directly on the eye (cornea) and gently roll finger away from the lens.
- Look down and slowly release the lower lid.
- Look straight ahead and slowly release the upper lid.
- Blink gently.

LENS REMOVAL INSTRUCTIONS

- Wash and rinse your hands thoroughly, and dry completely with a clean, lint free towel.
- Blink fully several times.
- While looking up, use the tip of your finger to slide the lens down onto the white part of the eye.
- Remove the lens by pinching gently between thumb and forefinger. Do not pinch the eye tissue.
- If the lens is difficult to remove, instill a lubricating and rewetting drop and try again after several minutes.
- Never use tweezers, suction cups, sharp objects or your finger nails to remove lenses from the lens container or your eyes.

If you experience problems with lens removal (lens decentered or damaged), see **WHAT TO DO IF A PROBLEM OCCURS** in the Adverse Effects section above.

BASIC INSTRUCTIONS FOR CARE OF LENSES

- Each time lenses are removed from the eye they must be properly cleaned, rinsed, and disinfected before reuse.
 - o The eye care professional should recommend and provide instructions for an appropriate lens care system.
 - o Lens care products have different uses and instructions. To avoid eye problems or damage to your lenses, always read and carefully follow the manufacturer's instructions for the product(s) used.
 - o Many lens care products require a rub and rinse step. If so, follow the lens care manufacturer's instructions for solution quantity and rub and rinse time to reduce the risk of serious eye infections.
- Soaking and Storing Your Lenses:
 - o Use only fresh contact lens care solution each time you soak (store) your lenses.
 - o The amount of time you can store lenses before cleaning, rinsing, and disinfection steps need to be repeated will vary depending on the lens care product used.
 - o 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. To "top-off" means to add fresh solution to solution that has been sitting in your case.
- After opening, discard any remaining solution after the period recommended by the product's manufacturer.
- Do not use products designed only for hard or rigid gas permeable lenses.
- Never use heat with lens care solutions or to disinfect lenses.
- Never use water, saline solution, or rewetting drops to disinfect your lenses. These solutions will not disinfect your lenses. Not using the recommended disinfecting solution can lead to severe infection, vision loss or blindness.

BASIC INSTRUCTIONS FOR THE LENS CASE

Contact lens care solutions and contact lens cases vary and have different purposes and instructions for use. Some cases are intended exclusively for storing contact lenses (sometimes referred to as a lens flat pack or lens storage case), while others are specially designed to contain a neutralizing disc for use with hydrogen peroxide cleaning and disinfecting systems. If not being worn on a daily basis, lenses that have been cleaned and disinfected can be stored in the unopened case for a period of time that varies depending on the contact lens solution and lens case used. Always follow the instructions provided by the manufacturer for the lens care products used.

- The eye care professional should instruct the patient on how to use the recommended lens care solution(s) and lens case.

- Contact lens cases can be a source of bacterial growth and require proper cleaning, drying and replacement to avoid contamination or damage to lenses:
 - o Clean contact lens cases with an appropriate contact lens solution and dry according to lens case instructions. Drying instructions, such as air-drying or wiping with lint-free towel, may vary depending on the lens case used.
 - o Replace contact lens cases at least once every 3 months, or as recommended by the lens case manufacturer.
 - o Replace specially designed lens cases containing a neutralizing disc according to manufacturer directions, or sooner if cleaned and disinfected lenses cause burning and stinging.
 - o Do not store your lenses or rinse your lens case with water or any non-sterile solution. Only use fresh lens care solution in order to avoid contamination of your lenses or lens case. Use of non-sterile solution can lead to severe infection, vision loss or blindness.

CONTENTS OF CONTAINER

Each lens is packaged in a foil-sealed plastic blister pack, which contains phosphate buffered saline solution containing 0.2% vinylpyrrolidone/dimethylaminoethylmethacrylate copolymer (VP/DMAEMA Copolymer), and is steam sterilized.

The blister package is marked with the base curve, diameter, dioptic power, lens print pattern/color, manufacturing lot number and expiration date.

Lenses are supplied in cartons containing up to 6 individually sealed contact lenses.

REFERENCES

Schein OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The Relative Risk of Ulcerative Keratitis Among Users of Daily-Wear and Extended-Wear Soft Contact Lenses. *N Eng J Med.* 1989; 321(12):773-83.

ABBREVIATIONS AND SYMBOLS USED ON LABELING

ABBREVIATIONS / SYMBOLS	DEFINITIONS
BC	Base Curve
DIA	Diameter
PWR	Power
D	Diopter (lens power)
L	Left
R	Right
VP/DMAEMA	Vinylpyrrolidone/Dimethylaminoethylmethacrylate
	Packaging waste license sign
	Batch code
	Use-by date
EXP	Expiration date (Use-by date)
	Sterilized using steam
	ISO 639-1 Two letter code for the language (Example shown: English)
	European conformity mark
	Caution
	Consult instructions for use
	Do not use if blister package is damaged
	Manufacturer
	Authorized Representative in the European Community
	Caution: Federal Law (United States) restricts this device to sale by or on the order of a licensed eye care professional.



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