PROFESSIONAL FITTING GUIDE

FOR

Hioxifilcon B
Soft Contact Lenses for Daily Wear

DESCRIPTION OF LENSES

The non-ionic lens material, Hioxifilcon B, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 52% Hioxifilcon B and 48% water by weight when immersed in normal saline solution buffered with either sodium bicarbonate or sodium perforate. The lens is available in clear and with a blue visibility-handling tint, phthalocyanato (2) - (copper).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The Hioxifilcon B spherical and toric visibly tinted soft contact lens is a hemispherical shell with the following parameters:

PARAMETER	VALUE
Diameter:	12.5 mm to 16.5mm
Center Thickness:	Varies with power (0.15mm at –3.00D)
Base Curve:	6.0 to 10.0 in 0.1mm steps
Sphere Power Range:	-20.0D to +20.0D in 0.1D steps
Cylinder Power Range:	-0.25 to -8.00 in 0.1D steps
Axis:	0° to 360° in 1° steps
Prism:	1.20 to 1.50

The physical properties of the lenses are:

PROPERTY	VALUE
Refractive Index	1.507 (dry); 1.425 (hydrated)
Light Transmission	greater than 95%
Water Content	48%
Specific Gravity	1.29 (dry); 1.14 (hydrated)
Oxygen Permeability (Dk Value)	15×10^{-11} Fatt Units (cm^2/sec)(ml O_2/ml x mm Hg @ 35°C), revised Fatt method

CAUTION

Due to the small number of patients enrolled in clinical investigations of lenses, all refractive powers, design configurations, or lens parameters available in the lens material were not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter. The potential impact of these factors on the patient's ocular health must be carefully weighed against the patient's need for refractive corrective. Therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

INDICATIONS

Hioxifilcon B soft spherical contact lenses for daily wear are indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia.and astigmatism of up to 0.75 Diopters or less that does not interfere with visual acuity. Lenses are available in clear and with blue visibility tint.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using either a heat or chemical disinfection system.

CONTRAINDICATIONS

DO NOT USE Hioxifilcon B soft contact lenses when any of the following conditions are present:

- Acute or subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctive, or eyelids.
- Severe insufficiency of lacrimal secretion (dry eyes).
- Corneal hypoesthesia (reduced corneal sensitivity), if not-aphakic.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, is solution, which is to be used to care for Hioxifilcon B soft contact lenses.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- Patients unable to follow lens care regimen or unable to obtain assistance to do so.

PATIENT SELECTION

Patient communication is vital. Patients who require visual correction but cannot adhere to the recommended care of Hioxifilcon B soft contact lenses should not be provided with this lens. All necessary steps in lens are and all precautions and warnings should be discussed and understood by the patient (*review Package Insert with patient*).

FITTING SYSTEM

Preliminary examinations should include the patient's refraction, keratometric readings, and biomicroscopy of the anterior segment. Lens design will dictate the required parameters. It is suggested that the patient be fitted closer to the original K reading than one would usually fit patients. Hioxifilcon lenses will stabilize very quickly on the eye, with less changes in parameters. Hioxifilcon B lenses will equilibrate faster with less change in the dry and the wet radius of curvature (BC).

K-reading	Base Curve
41.50 and down	Flat
41.75 to 44.00	Median
42.25 and up	Steep

FOLLOW-UP EXAMINATIONS

- Within one week of lens dispensing
- After three weeks of lens wear
- After seven weeks of lens wear
- After each six-month period of lens wear.

At the follow-up examinations, the patient should report good subjective quality of vision. Adaptation to vision with Hioxifilcon B soft contact lenses should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the practitioner should:

- Check distances and near acuity with lenses in place.
- Over-refract to verify lens prescription.
- Observe the position of the lens on the cornea. The lens should be centered and move on upward gaze and with a blink.
- Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
- Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
- Perform a slit-lamp examination with and without Fluorescein. Check for corneal edema, corneal abrasion, vascularization, corneal infiltrates, and perilimbal injection. Reinsert the lens only after all residual Fluorescein has dissipated from the eye.
- Clean the lens with a prophylactic surfactant cleaner, and examine for deposits, foreign bodies or physical imperfections of the lens surface.

LENS HANDLING

Wash and rinse hands thoroughly, making certain all soap residues have been rinsed away before drying with a lint-free towel. *It is suggested to wet the lens while in the eye using wetting drops before removal of the lens. Care should be used not to pinch the lens when removing it from the eye. Pinching the lens can reduce the life of the lens.*

Always start with the right lens first in order to avoid mixing the lenses. In removing the lenses, try to avoid touching the inside (concave) surface of the lens. It is possible, though not likely, that the lens might be inside out; therefore, check the lens by placing it on the index finger and examine its profile. If the edges of the lens tend to point outward, the lens is inside out. After removing the lens from its container assure that it is clean, clear and wet.

IN-OFFICE CLEANING , DISINFECTING, AND STORAGE

Each Hioxifilcon B soft contact lens received in the eye care practitioner's office is received sterile in a sealed vial with sterile buffered normal saline solution and labeled as to the parameters of the lens contained. To assure sterility, the vial should not be opened until ready for use.

To open the vial, break the aluminum seal and pull it off to expose the stopper. Upon removing the stopper, the lens may be removed and is ready for use. Any lens from an opened vial must be cleaned and disinfected before using.

CLEANING AND RINSING

A surfactant cleaner must be used with Hioxifilcon B soft contact lenses to ensure a clean lens surface. A single procedure is as follows:

Apply several drops to the lens, and then rub the surfaces of the lens against the palm of one hand with the index finger of the other hand or between the thumb and the forefinger for twenty seconds. *Do not fold the lens.* Thoroughly rinse both surfaces of the lens with a steady stream of fresh saline solution.

CHEMICAL (NOT-HEAT) LENS CARE SYSTEM

A sterile rinsing, storing, and disinfecting solution should be used to rinse and chemically disinfect Hioxifilcon B soft contact lenses. After cleaning the lens, rinse with a liberal amount of fresh disinfecting solution to remove loosened debris and traces of cleaner. The lens should then be placed in the plastic container supplied in a multi-purpose solution kit and filled with enough fresh disinfecting solution to completely submerge the lens. To ensure disinfecting, the lens must remain in the disinfecting solution for the recommended period of time as written on the disinfecting solution bottle. Before reinsertion, lenses should be rinsed with fresh sterile rinsing solution.

HEAT (THERMAL) LENS CARE SYSTEM

A premixed sterile preserved saline solution eliminates mixing errors and produces greater safety for storage and irrigation. After both surfaces have been cleaned; rinse the lens thoroughly with fresh saline solution. The lens should then be placed in its original vial and filled with enough fresh saline solution. Replace the stopper on the lens vial. A new aluminum cap should be put on the vial and crimped in place.

Since this lens is made from a non-ionic polymer Hioxifilcon B, it may be cleaned and disinfected by either heat or cold methods. The chemical and heat systems should not be alternated on the same lens. Practitioners usually use a heat method for the disinfecting of trial lenses. The Hioxifilcon B soft contact lens was developed to accommodate the heat method. Ensure that the lenses remain in the heat unit for the prescribed time.

LENS CARE DIRECTIONS

Refer to Package Insert.

STORAGE

The Hioxifilcon B soft contact lens must be stored in the recommended solutions. If exposed to the air, the lenses will dehydrate. If a lens dehydrates, it should be soaked ONLY in a soft contact lens storage solution until it returns to a soft, supple state. It should not be put on an eye until it has been put through a complete disinfecting cycle.

RECOMMENDED WEARING SCHEDULE

Close professional supervision is recommended to ensure safe and successful contact lens wear. If the patient complains of discomfort, decreased vision, ocular injection or corneal edema, the lens should be removed and the patient scheduled for examination. The problem may be relieved by putting the patient on a different wearing schedule or possibly by refitting the lenses.

RECOMMENDED LENS CARE PRODUCTS

The eye care practitioner should recommend a care system that is appropriate for the Hioxifilcon B soft contact lens. Each lens care product contains specific directions for use and important safety information, which should be read and carefully followed. Commercial solutions from Alcon, Allergan, CIBA etc., are all compatible with Hioxifilcon B lenses. The table below shows recommended solutions that were used for the FDA study

Daily Cleaner:	Alcon Opti-Free Daily Cleaner
Rinsing Solution:	Alcon Saline for Sensitive Eyes; Alcon Unisol
Disinfecting Solution:	Alcon Opti-Free (Rinse-Store and Disinfection Solution) for Soft Hydrophilic Lenses; Alcon Unisol Solutions
Lubricant/Rewetting Drops:	Alcon Opti-Free Rewetting Drops
Weekly Enzymatic Cleaner:	Alcon Optizyme Enzymatic Cleaner

WEARING SCHEDULE SHOULD BE DETERMINED BY THE EYE CARE PRACTITIONER.

Patients tend to over-wear the lenses initially. It is important not to exceed the initial wearing schedule. Regular check-ups, as determined by the eye care practitioner, are also extremely important. The maximum suggested wearing schedule for Hioxifilcon B soft contact lenses is as follows.

SUGGESTED WEARING SCHEDULE

Days	Continuous Hours	Days	Continuous Hours
1	3	8	8
2	3	9	8
3	4	10	10
4	4	11	12
5	6	12	14
6	6	13	15
7	8	14 and after	All waking hrs

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT Hioxifilcon B SOFT CONTACT LENSES ARE SAFE TO WEAR DURING SLEEP

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 FOR AT LEAST 15 TO 30 MINUTES AND IMMEDIATELY CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing Hioxifilcon B soft contact lenses or experienced with the lens should be reported to:

SpecialEyes LLC

PO Box 21417

Bradenton, FL 34204-1417

HOW SUPPLIED

Each Hioxifilcon B soft contact lens is supplied sterile in a sealed glass vial containing buffered normal saline solution. The vial is labeled with the base curve, power, diameter, manufacturing lot number, and the expiry date of the lens.

Manufactured for

SpecialEyes LLC

1 866 404 1060

PO Box 21417

Bradenton, FL 34204-1417