PROFESSIONAL FITTING GUIDE

FOR

Hioxifilcon D
Soft Contact Lenses for Daily Wear

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PRACTITIONER

DESCRIPTION OF LENSES

The non-ionic lens material, Hioxifilcon D, 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 46% Hioxifilcon D and 54% water by weight when immersed in normal saline solution buffered with sodium borate. The lens is available in 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 D spherical and toric visibly tinted soft contact lens is a hemispherical shell with the following parameters:

PARAMETER	VALUE
Diameter:	12.5 mm to 16.0mm
Center Thickness:	Varies with power (0.15mm at –3.00D)
Base Curve:	6.9 to 9.5 in 0.10mm steps
Sphere Power Range:	-25.0D to +25.0D in 0.1D steps
Toric Power Range:	15.0D
Cylinder Power Range:	-0.5 to -8.00 in 0.1D steps
Axis:	0° to 180° in 1° steps
Prism:	1.20 to 1.50

The physical properties of the lenses are:

PROPERTY	VALUE
Refractive Index	1.408 (hydrated)
Light Transmission	greater than 95%
Water Content	54%
Specific Gravity	1.299 (dry)
Oxygen Permeability (Dk Value)	23 x 10^{-11} Fatt Dk Units (cm^2/sec)(ml O_2/ml x mm Hg) ANSI Z80. 20-2004 polarographic method corrected for boundary-layer and edge effects.

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 D 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. The spherical lens may be worn by persons who exhibit astigmatism of up to 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters.

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 chemical disinfection system.

CONTRAINDICATIONS

DO NOT USE Hioxifilcon D 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, a solution, which is to be used to care for Hioxifilcon D 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 D 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 GUIDELINES

Although most aspects of the fitting procedure are identical for spherical and toric soft contact lenses, there are some additional guidelines to assure proper fit of Toric lenses. The Hioxifilcon D soft contact Toric lens is a prism-ballasted design and is prismatically stabilized. The Hioxifilcon D soft contact Toric lens has two diagnostic marks in the 3 and 9 o'clock positions to enable assessment of the lens orientation.

For fitting monovision patients, refer to the Monovision Fitting Guidelines.

Pre-Fitting Examination

A pre-fitting patient history and examination are necessary to:

- Determine whether a patient is a suitable candidate for daily wear contact lenses (consider patient hygiene and mental and physical state)
- Make ocular measurements for initial contact lens parameter selection, and
- Collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include a thorough case history, a spherocylindrical refraction, keratometry, tear assessment and biomicroscopic examination.

Lens Power Selection

A spectacle refraction should be performed to establish the patient's baseline refractive status and to select the trial lens power. Remember to compensate for vertex distance if the refraction is greater than -4.00D.

If selecting a trial lens, select a lens with a prescription most similar to the patient's refractive needs, or order a diagnostic lens to the prescription which most closely matches that of the patient after taking into account spherical equivalent and vertex calculations.

Lens Base Curve Selection

Corneal curvature measurements should be performed to establish the patient's baseline ocular status. A properly fit lens will center and completely cover the cornea (no limbal exposure), have sufficient movement with blink to provide tear exchange under the contact lens and be comfortable.

The lens should move freely when manipulated digitally with the lower lid, and then return to its properly centered position when released. If resistance is encountered when pushing the lens up, the lens is fitting tightly and should not be dispensed to the patient.

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 fewer changes in parameters. Hioxifilcon D 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

Lens Evaluation

Hioxifilcon D lenses will stabilize quickly on the eye. Place the lens on the eye and allow the lens to remain on the eye for at least 5 minutes for it to equilibrate. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

Lens power (Spherical):
A spherical over-refraction should be performed to determine the final lens power after the fit is judged to be acceptable. The spherical over-refraction should be combined with the trial lens power to determine the final lens prescription. The patient should experience good visual acuity with the correct lens power unless there is excessive residual astigmatism.

Example:

Diagnostic lens:	-3.00D
Spherical over-refraction:	-0.25D
Final lens power:	-3.25D

Lens Cylinder and Axis Orientation (Toric Lens):

The Hioxifilcon D soft contact Toric lens has two diagnostic marks in the 3 and 9 o'clock positions to enable assessment of the lens orientation.

The marks may stabilize somewhat clockwise or counter clockwise from the horizontal meridian at an angle and still enable you to fit a toric lens for that eye, as long as it always returns to the same position after movement (drift axis). The deviation can be compensated for in the final prescription. The objective is to ensure that the position the lens assumes near the 3 and 9 o'clock position, the drift position must be stable and repeatable. With full eye movement or heavy blink, you may see the marks swing away, but they must return quickly to the original stable position. If the lens does not return quickly, you may need to select a different lens.

The marks usually stabilize in the 180° position (3 and 9 o'clock positions). If they do, calculation of the lens power will be straight forward. The180° position is not a must; however, the absolute requirement is that the axis position be stable and repeatable.

Sometimes the diagnostic marks will stabilize clockwise or counter clockwise of the180° position. Because the final lens will orientate on the eye with the same deviation, the drift of the axis must be added or subtracted from the refractive axis. You can use an axis reticle in the slit lamp or use a line-scribed lens in a spectacle trial frame to measure or estimate the drift angle of the cylinder axis.

If the lens is rotating to the right, then the degree of rotation is subtracted from the refractive axis. If the lens is rotating to the left, then the degree of rotation is added to the refractive axis.

Lens Power (Toric Lens):
When the diagnostic lens has its axis aligned in the same meridian as the patient's refractive axis, spherocylindrical refraction over the lens may be performed and visual acuity determined. However, in the case of crossed axes, such as when the diagnostic lens axis is different from the spectacle cylinder axis, it is not advisable to over-refract because of the difficulty in computing the resultant power.
In fitting soft contact lenses, it is customary to prescribe the full power in the sphere. In the cylinder, however, any lens rotation is visually disturbing to the patient, so it's more practical to prescribe as weak a cylinder as possible.

For the sphere;
If Rx > +/- 4.00D, compensate for the vertex distance.
If Rx < +/- 4.00D, vertex distance compensation is not necessary.

For the cylinder:
Adjust the axis by the drift angle.
Choose a cylinder which is +/- 0.50D from the refractive cylinder.

Characteristics of a Tight (Steep) Lens

A steep fitting lens may exhibit one or more of the following characteristics: insufficient movement with the blink, conjunctival indentation, and resistance when pushing the lens up digitally with the lower lid.
A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

Characteristics of a Loose (Flat) Lens

If the lens is too flat, it may: decenter, especially on post-blink, have a tendency to edge lift inferiorly and is on the lower lid, rather than positioning between the sclera and palpebral conjunctiva, have a tendency to be uncomfortable and irritating with fluctuating vision, have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

Criteria of a Well-Fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well fitted lens and can be dispensed.

Follow-Up Care

Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for the follow up:

- 24 hours
- 10 days
- 1 month

- 3 months
- Every six months thereafter

At the initial follow-up evaluations the eye care professional should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

a. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear. With lenses in place on the eyes, evaluate fitting performance to assure that criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
b. After the lens removal, instill sodium fluorescein [unless contraindicated] into the eyes and conduct a thorough biomicroscopy examination.
    1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
    2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
    3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the criteria of a well-fitted lens are not satisfied during any follow-up examination, the patients should be refitted with a more appropriate lens.

MONOVISION FITTING GUIDELINES

Patient Selection

A. Monovision Needs Assessment
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 [1] diopter) in one eye may not be a good candidate for monovision with Hioxifilcon D Contact Lenses.

Occupational and environmental visual demands should be considerered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:
(1). Visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
(2). Driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. Patient Education
All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

Eye Selection

A. Ocular Preference Determination Methods
Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

Method 1 – Determine which eye is the "sighting dominant eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 – Determine which eye will accept the added power with the least reduction in vision. Lace a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. Refractive Error Method
For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. Visual Demands Method
Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.
Example:
A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

Special Fitting Considerations

Unilateral Lens Correction
There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.
Example:
A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.
A presbyopic patient requiring a +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around room at both near and distant objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and than graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below.
- Having a third contact lens (distance power) to use when critical distance viewing is needed.
- Having a third contact lens (near power) to use when critical near viewing is needed.
- 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 those patients who cannot meet state licensing requirements with a monovision correction.
- Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions.
- Reverse the distance and near eyes if a patient is having trouble adapting.
- Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
- Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye care professional in conjunction with the patient after carefully considering the patient's needs.

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 D soft contact lens received in the eye care practitioner's office is received sterile in a sealed vial with sterile borate buffered 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 D 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 LENS CARE SYSTEM

A sterile rinsing, storing, and disinfecting solution should be used to rinse and chemically disinfect Hioxifilcon D 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.

LENS CARE DIRECTIONS

Refer to Package Insert.

STORAGE

The Hioxifilcon D 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 D 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 D lenses. The table below shows recommended solutions:

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 D 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 D** 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 D soft contact lenses or experienced with the lens should be reported to:

SpecialEyes LLC
PO Box 21417
Bradenton, FL 34204 USA

HOW SUPPLIED

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

Manufactured for
SpecialEyes LLC
PO Box 21417
Bradenton, FL 34204 USA