IMPORTANT: Please read carefully and keep this information for future use.

This fitting guide is intended for the eyecare practitioner, but should be made available to the patient upon request. The eyecare practitioner should provide the patient with the wearer's guide that pertains to the patients prescribed lens.

clear1-day® (HIOXIFILCON A) DAILY DISPOSABLES SOFT CONTACT LENS (CLEAR AND VISIBILITY TINT)

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

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Description of Lens:

The **clearl-day®** **(Hioxifilcon** A) **Daily Disposables Soft Contact Lens** is available as a single vision spherical lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

Material Characteristics:

The non-ionic lens material, (hioxifilcon A) is a random co-polymer of 2-hydroxyethyl methacrylate and glycerol methacrylate cross-linked with ethylene glycol dimethacrylate. It consists of 42% hioxifilcon A and 58% water by weight when immersed in a buffered saline solution. The lens is available with a pale blue visibility handling tint, color additive 'Reactive Blue 4' 21CFR Part 73.3121. The hioxifilcon A name has been adopted by the United States Adopted Names Council (USAN).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, 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 hydrophilic characteristic allows aqueous solutions to enter the lens and in its fully hydrated state and the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index at 21^{o}C	1.4011(wet)
Light Transmission	> 95%
Surface Character	Hydrophilic
Water Content at 21^{o}C	59.77%
Specific Gravity at 21^{o}C	1.086(wet)
Oxygen Permeability at 34-36 ^{o}C	25.38 x 10^{-11} (cm^2/sec)(mlO_2/ml x mmHg), (revised FATT method)

The lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera with the following dimensions:

Chord Diameter:	14.2 mm
Centre Thickness:	0.09 mm
Base Curve:	8.7 mm
Powers:	+6.00 to +0.50 Dioptres in 0.25 D increment -0.50 to -6.00 Dioptres in 0.25 D increment -6.50 to -10.00 Dioptres in 0.50 D increment

ACTION:

In its hydrated state, the **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens,** when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

INDICATIONS:

Intended Use:

The **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** is indicated for daily wear single use only for the optical correction (except for plano lenses) of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The lens is intended to be worn once and then discarded at the end of each wearing period on a daily basis. The patient should be instructed to start the next wearing period with a new lens.

CONTRAINDICATIONS (REASONS NOT TO USE):

DO NOT USE the **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** when any of the following conditions are present:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, 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 lens.
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lens or use of contact lens solutions.
- Any active corneal infection (bacterial, fungi, or viral).
- If eyes become red or irritated.
- Patients unable to follow the daily disposable lens care schedule
- Advise patient not to wear **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** while sleeping.

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 parameter, the eyecare 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 correction. Therefore the continuing ocular health of the patient and the lens performance on the eye should be carefully monitored by the prescribing eyecare practitioner.

WARNINGS:

Please reference Warnings in the Package Insert included in this submission.

PRECAUTIONS:

Please reference Precautions in the Package Insert included in this submission.

ADVERSE REACTIONS:

Please reference Adverse Reactions in the Package Insert included in this submission.

PATIENT SELECTION:

The **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** is intended for patients that requires optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism.

The lenses are also intended for patients, whom have undergone treatment of acute or chronic ocular pathologies such as, bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post surgical conditions resulting from cataract extraction an corneal surgery, to be used as a therapeutic bandage to relieve corneal pain, at the sole discretion and under direct supervision of a qualified and licensed eyecare professional.

With the cosmetic effects, such as tints, under the sole discretion and direct supervision of a qualified eyecare professional, the lenses are also intended for use as prosthetic devices for sighted and non-sighted eyes, with or without lens power.

Patient communication is vital. Patients who require visual correction but can not adhere to the recommended wearing schedule of **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** should not be provided with this lens. All necessary precautions and warnings should be discussed and understood by the patient *(review Package Insert with the patient.)*

FITTING PROCEDURE FOR clearl-day® (Hioxifilcon A) Daily Disposables Soft Contact Lens

1) 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 (refer to contradictions)
Collect and record baseline clinical information to which post-fitting examination results can be compared.
Make ocular measurements for initial contact lens parameter selection

2) Parameter Selection

The preferred fitting method is by use of a trial lens, selecting the steeper base curve as first choice and then evaluate the **CRITERIA OF A WELL FITTED LENS.**

The alternative method is to determine the K readings and apply the following

Average K Reading	Suggested Lens Design
39.50 - 41.50 and higher	8.7 mm base curve / 14.2 mm Diameter

Lens power can be calculated from spectacle Rx

Sphere Lenses:
First convert the spectacle Rx in minus cylinder form (if applicable), compensate the power of both major meridians for a vertex distance of 0mm and then add half the cylinder power to the sphere.

Example:

Rx at 12mm vertex distance	-5.00 -1.00 x180
Power on horizontal meridians	-5 -00 @ 12 mm vertex compensate to -4.75 @ 0 vertex
Power on vertical meridians	-6.00 @ 12 mm vertex compensate to -5.50 @ 0 vertex
Rx at 0mm vertex distance	-4.75, -0.75 x1 80

Add half the cylinder to the sphere and round to the higher 0.25 step
(-4.75) + (-0.7512) = -5.25 final power of the lens

CLINICAL ASSESSMENT:

1. Criteria of a Well-Fitted Lens

The criteria of a well fitted lens is one which centers easily after a blink, bridges the limbus and extends onto the sclera about 1.25mm, lags downward about 1.0 to 1.5

mm on upward gaze and does not move excessively as a result of blinking or exaggerated eye movements.

After the trial lens has settled on the eye (5-10 minutes), manipulate the lens using lid pressure and observe for indications of excessive tightness. The lens should move freely and easily with slightest pressure and return to the centered position when released.

Movement of the lens on the eye is very important in assessing the fit and performance of the lens. In primary gaze, slight vertical post-blinking lens movement should occur. On upward gaze, the lens should sag approximately 1-1.5 mm.

2. Characteristics of a Tight (Steep) Lens

A tight (steep) lens does not move easily on the cornea with slight pressure.

3. Characteristics of a Loose (Flat) Lens

A loose (flat) lens sags more than 2.0 mm on upward gaze.

FOLLOW-UP CARE:

1. Follow-up examinations are recommended by the eyecare practitioner, they are necessary to ensure continued successful contact lens wear.
2. Prior to a follow up examination, the contact lens should be worn for at least one continuous hour and the patient should be asked to identify any problems which might be occurring related to contact lens wear.
3. With lenses in place on the eyes, evaluate the fitting performance to assure the criteria of a well-fitted lens continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.
4. After the lens removal, conduct a thorough bio-microscopy examination.
    a. The presence of vertical corneal striate in the posterior central cornea and/ or cornea neovascularization is indicative of excessive corneal edema.
    b. The presence of corneal staining and/ or limbal-conjunctival hypereremia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear and/ or a poorly fitting lens.
    c. Papillary conjunctival changes may be indicative of an unclean and / or damaged lens.

If any of the above observations are considered as abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to its optimal conditions. If the **Criteria of a Well-Fitted Lens** is not satisfied during any follow-up examinations, the patient should be refitted with a more appropriate lens.

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

Monovision Fitting Guidelines

1. 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 1.50 diopter) in one eye may not be a good candidate for monovision with the **clearl-day® (Hioxifilcon** A**) Daily Disposables Soft Contact Lens**.

   Occupational and environment visual demands should be considered. 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 potential hazardous activities; and
   (2) driving automobiles (eg. driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised not to 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, as well as other presbyopic contact lenses, or other alternative, 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.

2. Eye Selection

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

A. Ocular Preference Determination Methods

Method 1 – Determine which eye is the "sight 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 latest reduction in vision. Place 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 of 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.

3. Special Fitting Consideration

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 diopter myopic in the right eye and -1.50 diopter myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. 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 optical reading performance, prescribe the least plus (most minus) of the power.

5. 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 and base curve selection described earlier in the guide.

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 of fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distance 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 (eg. typewritten copy) at first and then graduate to news print and finally smaller type sizes.

After the patient's performance under the above conditions are 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.

6. 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.

7. Other suggestions

   The success of 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 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 sure 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 power 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 eyecare practitioner in conjunction with the patient after carefully considering the patient's needs.

   All patients should be supplied with a copy of the **clearl-day® (Hioxifilcon A) Daily Disposables Soft Contact Lens** Patient Instruction/ Wearer's Guide.

INSTRUCTIONS FOR MONOVISION WEARER:

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that available with monovision may be accompanied by a vision compromises that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a

feeling of slight imbalance may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persists, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers licenses requirements with monovision correction.

- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eyecare practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

  If you require very sharp near vision during prolonged close work, you may want to have additional contact lens prescribed so that both eyes corrected for near when sharp near binocular vision is required.

- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eyecare practitioner.

- It is important that you follow your eyecare practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.

- The decision to be fit with monovision correction is most appropriately left to the eyecare practitioner in conjunction with you, after carefully considering and discussing your needs.

At the follow up examinations, the patient should report good subjective quality of vision. Adaptation to the vision with **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** should occur almost immediately and should definitely be reported within the first (1 week) follow-up visit. At these follow-up visits the eyecare practitioner should:

1. Check distance and near acuity with lens in place
2. Over-refract to verify lens prescription
3. Observe position of lens on the cornea. The lens should be centered and move on upward gaze and with blink.
4. Evert the lids to examine the tarsal conjunctiva and check for incidence of giant papillary conjunctivitis.
5. Remove the lens. Check corneal curvature. There should be no substantial changes in either meridian.
6. 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.

LENS HANDLING (in-office cleaning)

Wash and rinse hands thoroughly, making certain that 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. Always start with the right eye first in order to avoid mixing the lenses. When handling the lens, 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.

Each **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** is received in the eyecare practitioner's office in a sterile blister pack. To assure sterility the blister pack should not be opened until ready for use.

To open the blister pack pull back the lid where indicated. Upon removing the cover the lens may be removed and is ready for use.

clearl-day® (Hioxifilcon A) **Daily Disposables Soft Contact Lens** are not reused in diagnostic procedures.

CLEANING:

The **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** are designed as a Daily Disposable lens.

The lens is intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a new lens. Emergency lens cleaning and disinfection is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times

RECCOMENDED 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 lens.

Patients tend to overwear the lens initially. It is important not to exceed the wearing schedule. Regular check ups, as determined by the eyecare practitioner, are also extremely important. The maximum suggested wearing schedule for the **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** is suggested below.

DAY	1	2	3	4	5	6
HOURS	6	8	10	12	14	All working hours

STUDIES HAVE NOT BEEN COMPLETED TO SHOW THAT THE clearl-day® (Hioxifilcon A) **Daily Disposables Soft Contact Lens " IS SAFE TO WEAR DURING SLEEP**

The **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** is intended to be worn once and then discarded at the end of each wearing period. The patient should be instructed to start the next wearing period with a new lens.

EMERGENCIES:

Emergency lens cleaning and disinfection is not recommended. The patient should be reminded to have replacement lenses or back-up spectacles available at all times.

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

FLUSH EYES IMMEDIATELY WITH TAP WATER AND IMMEDIATELY CONTACT YOUR EYECARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY
REPORTING OF ADVERSE REACTIONS

Practitioners should report any adverse reactions to **clearl-day® (Hioxifilcon** A) **Daily Disposables Soft Contact Lens** within 5 days to at the address below.

Additional Package Insert and Patient Instruction/ Wearer's Guide are available from:

Clearlab SG Pte. Ltd.
139 Joo Seng Road,
Singapore 368362
Tel: +65 6749 1090
Fax: +65 6282 3953
Email: Regulatory@clearlab.com
Website: www.clearlab.com

HOW SUPPLIED

Each lens is supplied sterile in blister packs containing buffered saline solution. The blister pack is marked with dioptic power, Single Patient Use, Rx symbol, sterile symbol, composition of the lens, manufacturing lot number and expiration date of the lens. The blister pack is also marked as 'NOT FOR INDIVIDUAL RESALE'.

Clearlab SG Pte. Ltd.
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